**Other side effects**

**Very common** (may affect more than 1 in 10 people):
- Bleeding
- Increases in liver enzymes

**Common** (may affect up to 1 in 10 people):
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts
- pink patches on your skin – these are more likely to appear in the area you have been injected with Clexane Syringes
- skin rash (hives, urticaria)
- itchy red skin
- bruising or pain at the injection site
- decreased red blood cell count
- high platelet counts in the blood
- headache

**Uncommon** (may affect up to 1 in 100 people):
- sudden severe headache – this could be a sign of bleeding in the brain
- a feeling of tenderness and swelling in your stomach – you may have bleeding in your stomach
- large red irregularly shaped skin lesions with or without blisters
- skin irritation (local irritation)
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem

**Rare** (may affect up to 1 in 1,000 people):
- severe allergic reaction – the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- increased potassium in your blood – this is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test
- an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- hair loss
- osteoporosis (a condition where your bones are more likely to break) after long term use
- tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic
- loss of control over your bladder or bowel (so you cannot control when you go to the toilet)
- hard mass or lump at the injection site.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Clexane Syringes

Do not use this medicine after the expiry date shown on the carton or syringe blister container. The expiry date refers to the last day of that month. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine, if your doctor tells you to.

If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Do not take the syringe out of the box until you need to use it.

Do not use this medicine if you notice a breach in the syringe, particulate matters in the solution, or an abnormal colour of the solution (see “What Clexane Syringes look like and the contents of the pack”).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.



## 6 Contents of the pack and other information

**What Clexane Syringes contains**

The active substance is enoxaparin sodium
Each mL contains 100mg enoxaparin sodium, equivalent to 10,000 IU of anti-Xa activity
Each pre-filled syringe of 0.2mL contains 2,000 IU (20mg) of enoxaparin sodium
Each pre-filled syringe of 0.4mL contains 4,000 IU (40mg) of enoxaparin sodium
Each pre-filled syringe of 0.6mL contains 6,000 IU (60mg) of enoxaparin sodium
Each pre-filled syringe of 0.8mL contains 8,000 IU (80mg) of enoxaparin sodium
Each pre-filled syringe of 1mL contains 10,000 IU (100mg) of enoxaparin sodium
The other ingredient is water for injections

**What Clexane Syringes looks like and contents of the pack**

Clexane Syringes are type 1 glass pre-filled syringes fitted with injection needles. Clexane Syringes comes in packs of 6 or 10 syringes.

**Product Licence Holder and Manufacturer**

Clexane Syringes are manufactured by Sanofi Winthrop Industrie, 180 rue Jean Jaures, 94700 Maisons-Alfort, France and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL 15184/0742 Clexane 2,000IU (20mg)/0.2ml Syringes / Clexane 4,000IU (40mg)/0.4ml Syringes / Clexane 6,000IU (60mg)/0.6ml Syringes / Clexane 8,000IU (80mg)/0.8ml Syringes / Clexane 10,000IU (100mg)/1ml Syringes

Clexane Syringes is a registered trademark of Sanofi Mature IP

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# Clexane® 2,000IU (20mg)/0.2ml Syringes / Clexane® 4,000IU (40mg)/0.4ml Syringes / Clexane® 6,000IU (60mg)/0.6ml Syringes / Clexane® 8,000IU (80mg)/0.8ml Syringes / Clexane® 10,000IU (100mg)/1ml Syringes

(enoxaparin sodium)

## Patient Information Leaflet

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Clexane 2,000IU (20mg)/0.2ml Syringes, Clexane 4,000IU (40mg)/0.4ml Syringes / Clexane 6,000IU (60mg)/0.6ml Syringes/ Clexane 8,000IU (80mg)/0.8ml Syringes / Clexane 10,000IU (100mg)/1ml Syringes and will be referred to as Clexane Syringes throughout the rest of this leaflet.

**What is in this leaflet**


1 What Clexane Syringes are and what they are used for
2 What you need to know before you use Clexane Syringes
3 How to use Clexane Syringes
4 Possible side effects
5 How to store Clexane Syringes
6 Contents of the pack and other information


## 1 What Clexane Syringes are and what they are used for

Clexane Syringes contain the active substance called enoxaparin sodium. This belongs to a group of medicines called ‘low molecular weight heparin’ or LMWH.

**How Clexane Syringes work**

Clexane Syringes work in two ways:
1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm.
2) Stopping new blood clots from forming in your blood.

**What Clexane Syringes are used for**

Clexane Syringes can be used to:
- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
  - before and after an operation
  - when you have a short-term illness and will not be able to move around for some time.
  - if you have experienced a blood clot due to cancer to prevent further clots from forming
- Stop blood clots from forming when you have unstable angina (where not enough blood gets to your heart) or after a heart attack
- Stop blood clots from forming in the tubes of your dialysis machine (used for people with severe kidney problems).

## 2 What you need to know before you use Clexane Syringes

**Do not use Clexane Syringes if:**
- you are allergic to:
  - enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6)
  - heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin. Signs of an allergic reaction include: rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes.
- you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) within the last 100 days
- you have antibodies against enoxaparin in your blood
- you are bleeding heavily or have a condition with a high risk of bleeding, such as:
  - stomach ulcer, recent surgery of the brain or eyes, or recent bleeding stroke.
- you are using Clexane Syringes to treat blood clots and are going to have within 24 hours:
  - a spinal or lumbar puncture
  - an operation with epidural or spinal anaesthesia.

Do not use Clexane Syringes if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Clexane Syringes.

**Warnings and precautions**

Clexane Syringes should not be interchanged with other ‘low molecular weight heparins’ such as nadroparin, tinzaparin or dalteparin. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Clexane Syringes if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have a history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high levels of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section 2, ‘Other medicines and Clexane Syringes’)
- you have any problem with your spine or you have had spinal surgery.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Clexane Syringes.

For patients receiving doses higher than 210 mg/day, this medicine contains more than 24 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult.

**Tests and checks**

You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

**Use in children and adolescents**

The safety and efficacy of Clexane Syringes has not been evaluated in children or adolescents.

**Other medicines and Clexane Syringes**

Tell your doctor or pharmacist if you are taking or might take any other medicines.
- warfarin – used for thinning the blood
- aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see section 3, ‘Changing anticoagulant medicine’)
- dextran injection – used as a blood replacer
- ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory medicines which are used to treat pain and swelling in arthritis and other conditions
- prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- medicines which increase potassium levels in your blood such as potassium salts, water pills, and some medicines for heart problems.

**Operations and anaesthetics**

If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Clexane Syringes.

**Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

**Driving and using machines**

Clexane Syringes do not affect the ability to drive and operate machinery.

It is advised that the trade name and batch number of the product you are using are recorded by your healthcare professional.

## 3 How to use Clexane Syringes

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- Your doctor or nurse will normally give you Clexane Syringes. This is because they need to be given as an injection.
- Clexane Syringes are usually given by injection underneath the skin (subcutaneous).
- Clexane Syringes can be given by injection into your vein (intravenous) after certain types of heart attack or operations.
- Clexane Syringes can be added to the tube leaving the body (arterial line) at the start of a dialysis session.
- Do not inject Clexane Syringes into a muscle.

**How much will be given to you**

- Your doctor will decide how much Clexane Syringes to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Clexane Syringes.

**1) Treating blood clots that are in your blood**

- The usual dose is 150 IU (1.5 mg) for every kilogram of your bodyweight once a day or 100 IU (1 mg) for every kilogram of your bodyweight twice a day.
- Your doctor will decide how long you should receive Clexane Syringes.

**2) Stopping blood clots from forming in your blood during operations or periods of limited mobility due to an illness**

- The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Clexane Syringes each day.
- If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Clexane Syringes each day.
- Your doctor will decide how long you should receive Clexane Syringes.

3) **Stopping blood clots when you have unstable angina or after you have had a heart attack**

- Clexane Syringes can be used for two different types of heart attack.
- The amount of Clexane Syringes given to you will depend on your age and the kind of heart attack you have had.

NSTEMI (Non-ST segment Elevation Myocardial Infarction) type of heart attack:
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Clexane Syringes.



STEMI (ST segment Elevation Myocardial Infarction) type of heart attack if you are under 75 years old:
- An initial dose of 3,000 IU (30 mg) of Clexane Syringes will be given as an injection into your vein.
- At the same time you will also be given Clexane Syringes as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Clexane Syringes.

STEMI type of heart attack if you are 75 years old or older:
- The usual dose is 75 IU (0.75 mg) for every kilogram of your bodyweight, every 12 hours.
- The maximum amount of Clexane Syringes given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Clexane Syringes.

For patients that have an operation called percutaneous coronary intervention (PCI):
- Depending on when you were last given Clexane Syringes, your doctor may decide to give an additional dose of Clexane Syringes before a PCI operation. This is by injection into your vein.

**4) Stopping blood clots from forming in the tubes of your dialysis machine**

- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.
- Clexane Syringes are added to the tube leaving the body (arterial line) at the start of a dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a futher dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your bodyweight, if necessary.

**Giving yourself an injection of Clexane Syringes**

If you are able to give Clexane Syringes to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately. Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

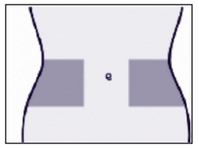
**Before injecting yourself with Clexane Syringes**

- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container
- Check the expiry date on the medicine. Do not use if the date has passed
- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe
- Make sure you know how much you are going to inject
- Check your stomach to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so talk to your doctor or nurse

**Instructions on injecting yourself with Clexane Syringes:**

**Preparing the injection site**

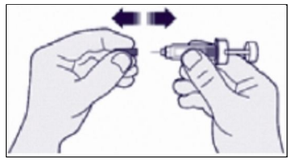
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
- Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
- Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

**Selecting your dose**

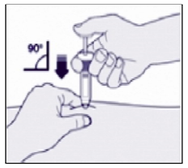
1) Carefully pull off the needle cap from the syringe. Throw away the cap.
- Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
- Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

**Injecting**

1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
   - Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.




3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out. You can now let go of the skin fold.

**When you have finished**

1) To avoid bruising, do not rub the injection site after you have injected yourself.
2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

**Changing anticoagulant medicine**

- **Changing from Clexane Syringes to blood thinners called vitamin-K antagonists (such as warfarin)**
  Your doctor will ask you to have blood tests called INR and tell you when to stop Clexane Syringes.

- **Changing from blood thinners called vitamin-K antagonists (such as warfarin) to Clexane Syringes**
  Stop taking the vitamin-K antagonist. Your doctor will ask you to have blood tests called INR and tell you when to start Clexane Syringes.

- **Changing from Clexane Syringes to treatment with direct oral anticoagulants**
  Stop taking Clexane Syringes. Start taking the direct oral anticoagulant 0 to 2 hours before the time you would have had the next injection, then continue as normal.

- **Changing from treatment with direct oral anticoagulants to Clexane Syringes**
  Stop taking the direct oral anticoagulant. Do not start treatment with Clexane Syringes until 12 hours after the final dose of the direct oral anticoagulant.

**If you use more Clexane Syringes than you should**

If you think that you have used too much or too little Clexane Syringes, tell your doctor or pharmacist or nurse immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Clexane Syringes, take them to a hospital casualty department straight away.

**If you forget to use Clexane Syringes**

If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

**If you stop using Clexane Syringes**

It is important for you to keep having Clexane Syringes injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

**Stop using Clexane Syringes and talk to a doctor or nurse straight away** if you get any signs of a severe allergic reaction (such as rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes).

**Stop using Clexane Syringes and seek medical attention immediately if you notice any of the following symptoms:**
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

Like other similar medicines to reduce blood clotting, Clexane Syringes may cause bleeding . This may be life-threatening. In some cases the bleeding may not be obvious.

**Talk to your doctor straight away if:**
- you have any bleeding that does not stop by itself
- you have signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling

Your doctor may decide to keep you under closer observation or change your medicine.

**You should tell your doctor straight away:**

- if you have any sign of blockage of a blood vessel by a blood clot such as:
  - cramping pain, redness, warmth, or swelling in one of your legs – these are symptoms of deep vein thrombosis
  - breathlessness, chest pain, fainting or coughing up blood – these are symptoms of a pulmonary embolism
- if you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may request you perform a blood test to check your platelet count.



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**Other side effects**

**Very common** (may affect more than 1 in 10 people):
- Bleeding
- Increases in liver enzymes

**Common** (may affect up to 1 in 10 people):
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts
- pink patches on your skin – these are more likely to appear in the area you have been injected with Lovenox Syringes
- skin rash (hives, urticaria)
- itchy red skin
- bruising or pain at the injection site
- decreased red blood cell count
- high platelet counts in the blood
- headache

**Uncommon** (may affect up to 1 in 100 people):
- sudden severe headache – this could be a sign of bleeding in the brain
- a feeling of tenderness and swelling in your stomach – you may have bleeding in your stomach
- large red irregularly shaped skin lesions with or without blisters
- skin irritation (local irritation)
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem

**Rare** (may affect up to 1 in 1,000 people):
- severe allergic reaction – the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- increased potassium in your blood – this is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test
- an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- hair loss
- osteoporosis (a condition where your bones are more likely to break) after long term use
- tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic
- loss of control over your bladder or bowel (so you cannot control when you go to the toilet)
- hard mass or lump at the injection site.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Lovenox Syringes

Do not use this medicine after the expiry date shown on the carton or syringe blister container. The expiry date refers to the last day of that month. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine, if your doctor tells you to.
If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Do not take the syringe out of the box until you need to use it.

Do not use this medicine if you notice a breach in the syringe, particulate matters in the solution, or an abnormal colour of the solution (see “What Lovenox Syringes look like and the contents of the pack”).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.



## 6 Contents of the pack and other information

**What Lovenox Syringes contains**
The active substance is enoxaparin sodium
Each mL contains 100mg enoxaparin sodium, equivalent to 10,000 IU of anti-Xa activity
Each pre-filled syringe of 0.2mL contains 2,000 IU (20mg) of enoxaparin sodium
Each pre-filled syringe of 0.4mL contains 4,000 IU (40mg) of enoxaparin sodium
Each pre-filled syringe of 0.6mL contains 6,000 IU (60mg) of enoxaparin sodium
Each pre-filled syringe of 0.8mL contains 8,000 IU (80mg) of enoxaparin sodium
Each pre-filled syringe of 1mL contains 10,000 IU (100mg) of enoxaparin sodium
The other ingredient is water for injections

**What Lovenox Syringes looks like and contents of the pack**
Lovenox Syringes are type 1 glass pre-filled syringes fitted with injection needles. Lovenox Syringes comes in packs of 6 or 10 syringes.

**Product Licence Holder and Manufacturer**
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PL 15184/0742 Lovenox 2,000IU (20mg)/0.2ml Syringes / Lovenox 4,000IU (40mg)/0.4ml Syringes / Lovenox 6,000IU (60mg)/0.6ml Syringes / Lovenox 8,000IU (80mg)/0.8ml Syringes / Lovenox 10,000IU (100mg)/1ml Syringes

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# Lovenox® 2,000IU (20mg)/0.2ml Syringes / Lovenox® 4,000IU (40mg)/0.4ml Syringes / Lovenox® 6,000IU (60mg)/0.6ml Syringes / Lovenox® 8,000IU (80mg)/0.8ml Syringes / Lovenox® 10,000IU (100mg)/1ml Syringes

(enoxaparin sodium)

## Patient Information Leaflet

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Lovenox 2,000IU (20mg)/0.2ml Syringes /Lovenox 4,000IU (40mg)/0.4ml Syringes /Lovenox 6,000IU (60mg)/0.6ml Syringes / Lovenox 8,000IU (80mg)/0.8ml Syringes /Lovenox 10,000IU (100mg)/1ml Syringes and will be referred to as Lovenox Syringes throughout the rest of this leaflet.

**What is in this leaflet**

1 What Lovenox Syringes are and what they are used for
2 What you need to know before you use Lovenox Syringes
3 How to use Lovenox Syringes
4 Possible side effects
5 How to store Lovenox Syringes
6 Contents of the pack and other information


## 1 What Lovenox Syringes are and what they are used for

Lovenox Syringes contain the active substance called enoxaparin sodium. This belongs to a group of medicines called ‘low molecular weight heparin’ or LMWH.

**How Lovenox Syringes work**
Lovenox Syringes work in two ways:
1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm.
2) Stopping new blood clots from forming in your blood.

**What Lovenox Syringes are used for**
Lovenox Syringes can be used to:
- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
  - before and after an operation
  - when you have a short-term illness and will not be able to move around for some time.
  - if you have experienced a blood clot due to cancer to prevent further clots from forming
- Stop blood clots from forming when you have unstable angina (where not enough blood gets to your heart) or after a heart attack
- Stop blood clots from forming in the tubes of your dialysis machine (used for people with severe kidney problems).

## 2 What you need to know before you use Lovenox Syringes

**Do not use Lovenox Syringes if:**
- you are allergic to:
  - enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6)
  - heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin. Signs of an allergic reaction include: rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes.
- you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) within the last 100 days
- you have antibodies against enoxaparin in your blood
- you are bleeding heavily or have a condition with a high risk of bleeding, such as:
  - stomach ulcer, recent surgery of the brain or eyes, or recent bleeding stroke.
- you are using Lovenox Syringes to treat blood clots and are going to have within 24 hours:
  - a spinal or lumbar puncture
  - an operation with epidural or spinal anaesthesia.

Do not use Lovenox Syringes if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Lovenox Syringes.

**Warnings and precautions**
Lovenox Syringes should not be interchanged with other ‘low molecular weight heparins’ such as nadroparin, tinzaparin or dalteparin. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Lovenox Syringes if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have a history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high levels of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section 2, ‘Other medicines and Lovenox Syringes’)
- you have any problem with your spine or you have had spinal surgery.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Lovenox Syringes.

For patients receiving doses higher than 210 mg/day, this medicine contains more than 24 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult.

**Tests and checks**
You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

**Use in children and adolescents**
The safety and efficacy of Lovenox Syringes has not been evaluated in children or adolescents.

**Other medicines and Lovenox Syringes**
Tell your doctor or pharmacist if you are taking or might take any other medicines.
- warfarin – used for thinning the blood
- aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see section 3, ‘Changing anticoagulant medicine’)
- dextran injection – used as a blood replacer
- ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory medicines which are used to treat pain and swelling in arthritis and other conditions
- prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- medicines which increase potassium levels in your blood such as potassium salts, water pills, and some medicines for heart problems.

**Operations and anaesthetics**

If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Lovenox Syringes.

**Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

**Driving and using machines**

Lovenox Syringes do not affect the ability to drive and operate machinery.

It is advised that the trade name and batch number of the product you are using are recorded by your healthcare professional.

## 3 How to use Lovenox Syringes

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- Your doctor or nurse will normally give you Lovenox Syringes. This is because they need to be given as an injection.
- Lovenox Syringes are usually given by injection underneath the skin (subcutaneous).
- Lovenox Syringes can be given by injection into your vein (intravenous) after certain types of heart attack or operations.
- Lovenox Syringes can be added to the tube leaving the body (arterial line) at the start of a dialysis session.
- Do not inject Lovenox Syringes into a muscle.

**How much will be given to you**

- Your doctor will decide how much Lovenox Syringes to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Lovenox Syringes.

**1) Treating blood clots that are in your blood**

- The usual dose is 150 IU (1.5 mg) for every kilogram of your bodyweight once a day or 100 IU (1 mg) for every kilogram of your bodyweight twice a day.
- Your doctor will decide how long you should receive Lovenox Syringes.

**2) Stopping blood clots from forming in your blood during operations or periods of limited mobility due to an illness**

- The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Lovenox Syringes each day.
- If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Lovenox Syringes each day.
- Your doctor will decide how long you should receive Lovenox Syringes.

**3) Stopping blood clots when you have unstable angina or after you have had a heart attack**

- Lovenox Syringes can be used for two different types of heart attack.
- The amount of Lovenox Syringes given to you will depend on your age and the kind of heart attack you have had.

NSTEMI (Non-ST segment Elevation Myocardial Infarction) type of heart attack:
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Lovenox Syringes.



STEMI (ST segment Elevation Myocardial Infarction) type of heart attack if you are under 75 years old:
- An initial dose of 3,000 IU (30 mg) of Lovenox Syringes will be given as an injection into your vein.
- At the same time you will also be given Lovenox Syringes as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Lovenox Syringes.

STEMI type of heart attack if you are 75 years old or older:
- The usual dose is 75 IU (0.75 mg) for every kilogram of your bodyweight, every 12 hours.
- The maximum amount of Lovenox Syringes given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Lovenox Syringes.

For patients that have an operation called percutaneous coronary intervention (PCI):
- Depending on when you were last given Lovenox Syringes, your doctor may decide to give an additional dose of Lovenox Syringes before a PCI operation.
  This is by injection into your vein.

**4) Stopping blood clots from forming in the tubes of your dialysis machine**
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.
- Lovenox Syringes are added to the tube leaving the body (arterial line) at the start of a dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a futher dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your bodyweight, if necessary.

**Giving yourself an injection of Lovenox Syringes**

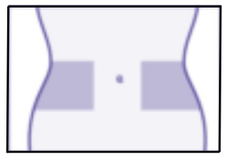
If you are able to give Lovenox Syringes to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately. Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

**Before injecting yourself with Lovenox Syringes**

- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container
- Check the expiry date on the medicine. Do not use if the date has passed
- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe
- Make sure you know how much you are going to inject
- Check your stomach to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so talk to your doctor or nurse

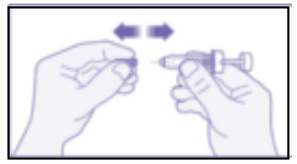
**Instructions on injecting yourself with Lovenox Syringes:**

**Preparing the injection site**
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
- Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
- Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

**Selecting your dose**
1) Carefully pull off the needle cap from the syringe. Throw away the cap.
- Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
- Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

**Injecting**

1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
   - Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.

3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out. You can now let go of the skin fold.

**When you have finished**

1) To avoid bruising, do not rub the injection site after you have injected yourself.
2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

**Changing anticoagulant medicine**

- **Changing from Lovenox Syringes to blood thinners called vitamin-K antagonists (such as warfarin)**
  Your doctor will ask you to have blood tests called INR and tell you when to stop Lovenox Syringes.

- **Changing from blood thinners called vitamin-K antagonists (such as warfarin) to Lovenox Syringes**
  Stop taking the vitamin-K antagonist. Your doctor will ask you to have blood tests called INR and tell you when to start Lovenox Syringes.

- **Changing from Lovenox Syringes to treatment with direct oral anticoagulants**
  Stop taking Lovenox Syringes. Start taking the direct oral anticoagulant 0 to 2 hours before the time you would have had the next injection, then continue as normal.

- **Changing from treatment with direct oral anticoagulants to Lovenox Syringes**
  Stop taking the direct oral anticoagulant. Do not start treatment with Lovenox Syringes until 12 hours after the final dose of the direct oral anticoagulant.

**If you use more Lovenox Syringes than you should**

If you think that you have used too much or too little Lovenox Syringes, tell your doctor or pharmacist or nurse immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Lovenox Syringes, take them to a hospital casualty department straight away.

**If you forget to use Lovenox Syringes**

If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

**If you stop using Lovenox Syringes**

It is important for you to keep having Lovenox Syringes injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

**Stop using Lovenox Syringes and talk to a doctor or nurse straight away** if you get any signs of a severe allergic reaction (such as rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes).

**Stop using Lovenox Syringes and seek medical attention immediately if you notice any of the following symptoms:**
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

Like other similar medicines to reduce blood clotting, Lovenox Syringes may cause bleeding . This may be life-threatening. In some cases the bleeding may not be obvious.

**Talk to your doctor straight away if:**
- you have any bleeding that does not stop by itself
- you have signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling

Your doctor may decide to keep you under closer observation or change your medicine.

**You should tell your doctor straight away:**

- if you have any sign of blockage of a blood vessel by a blood clot such as:
  - cramping pain, redness, warmth, or swelling in one of your legs – these are symptoms of deep vein thrombosis
  - breathlessness, chest pain, fainting or coughing up blood – these are symptoms of a pulmonary embolism
- if you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may request you perform a blood test to check your platelet count.



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**Other side effects**

**Very common** (may affect more than 1 in 10 people):
- Bleeding
- Increases in liver enzymes

**Common** (may affect up to 1 in 10 people):
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts
- pink patches on your skin – these are more likely to appear in the area you have been injected with Clexane Syringes
- skin rash (hives, urticaria)
- itchy red skin
- bruising or pain at the injection site
- decreased red blood cell count
- high platelet counts in the blood
- headache

**Uncommon** (may affect up to 1 in 100 people):
- sudden severe headache – this could be a sign of bleeding in the brain
- a feeling of tenderness and swelling in your stomach – you may have bleeding in your stomach
- large red irregularly shaped skin lesions with or without blisters
- skin irritation (local irritation)
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem

**Rare** (may affect up to 1 in 1,000 people):
- severe allergic reaction – the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- increased potassium in your blood – this is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test
- an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- hair loss
- osteoporosis (a condition where your bones are more likely to break) after long term use
- tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic
- loss of control over your bladder or bowel (so you cannot control when you go to the toilet)
- hard mass or lump at the injection site.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Clexane Syringes

Do not use this medicine after the expiry date shown on the carton or syringe blister container. The expiry date refers to the last day of that month. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine, if your doctor tells you to.
If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Do not take the syringe out of the box until you need to use it.

Do not use this medicine if you notice a breach in the syringe, particulate matters in the solution, or an abnormal colour of the solution (see “What Clexane Syringes look like and the contents of the pack”).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.



## 6 Contents of the pack and other information

**What Clexane Syringes contains**
The active substance is enoxaparin sodium
Each mL contains 100mg enoxaparin sodium, equivalent to 10,000 IU of anti-Xa activity
Each pre-filled syringe of 0.2mL contains 2,000 IU (20mg) of enoxaparin sodium
Each pre-filled syringe of 0.4mL contains 4,000 IU (40mg) of enoxaparin sodium
Each pre-filled syringe of 0.6mL contains 6,000 IU (60mg) of enoxaparin sodium
Each pre-filled syringe of 0.8mL contains 8,000 IU (80mg) of enoxaparin sodium
Each pre-filled syringe of 1mL contains 10,000 IU (100mg) of enoxaparin sodium
The other ingredient is water for injections

**What Clexane Syringes looks like and contents of the pack**
Clexane Syringes are type 1 glass pre-filled syringes fitted with injection needles. Clexane Syringes comes in packs of 6 or 10 syringes.

**Product Licence Holder and Manufacturer**
Clexane Syringes are manufactured by Sanofi-Aventis. S.A Avda. de Leganes, 62, 28925 Alcorcon-Madrid, Spain and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL 15184/0742 Clexane 2,000IU (20mg)/0.2ml Syringes / Clexane 4,000IU (40mg)/0.4ml Syringes / Clexane 6,000IU (60mg)/0.6ml Syringes / Clexane 8,000IU (80mg)/0.8ml Syringes / Clexane 10,000IU (100mg)/1ml Syringes

Clexane Syringes is a registered trademark of Sanofi Mature IP

Revision date: 25/08/23

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Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you

Ref:0742/250823/4/F

# Clexane® 2,000IU (20mg)/0.2ml Syringes / Clexane® 4,000IU (40mg)/0.4ml Syringes / Clexane® 6,000IU (60mg)/0.6ml Syringes / Clexane® 8,000IU (80mg)/0.8ml Syringes / Clexane® 10,000IU (100mg)/1ml Syringes

(enoxaparin sodium)

## Patient Information Leaflet

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Clexane 2,000IU (20mg)/0.2ml Syringes,Clexane 4,000IU (40mg)/0.4ml Syringes / Clexane 6,000IU (60mg)/0.6ml Syringes/ Clexane 8,000IU (80mg)/0.8ml Syringes / Clexane 10,000IU (100mg)/1ml Syringes and will be referred to as Clexane Syringes throughout the rest of this leaflet.

**What is in this leaflet**


1 What Clexane Syringes are and what they are used for
2 What you need to know before you use Clexane Syringes
3 How to use Clexane Syringes
4 Possible side effects
5 How to store Clexane Syringes
6 Contents of the pack and other information


## 1 What Clexane Syringes are and what they are used for

Clexane Syringes contain the active substance called enoxaparin sodium. This belongs to a group of medicines called ‘low molecular weight heparin’ or LMWH.

**How Clexane Syringes work**
Clexane Syringes work in two ways:
1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm.
2) Stopping new blood clots from forming in your blood.

**What Clexane Syringes are used for**
Clexane Syringes can be used to:
- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
  - before and after an operation
  - when you have a short-term illness and will not be able to move around for some time.
  - if you have experienced a blood clot due to cancer to prevent further clots from forming
- Stop blood clots from forming when you have unstable angina (where not enough blood gets to your heart) or after a heart attack
- Stop blood clots from forming in the tubes of your dialysis machine (used for people with severe kidney problems).

## 2 What you need to know before you use Clexane Syringes

**Do not use Clexane Syringes if:**
- you are allergic to:
  - enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6)
  - heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin. Signs of an allergic reaction include: rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes.
- you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) within the last 100 days
- you have antibodies against enoxaparin in your blood
- you are bleeding heavily or have a condition with a high risk of bleeding, such as:
  - stomach ulcer, recent surgery of the brain or eyes, or recent bleeding stroke.
- you are using Clexane Syringes to treat blood clots and are going to have within 24 hours:
  - a spinal or lumbar puncture
  - an operation with epidural or spinal anaesthesia.

Do not use Clexane Syringes if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Clexane Syringes.

**Warnings and precautions**
Clexane Syringes should not be interchanged with other ‘low molecular weight heparins’ such as nadroparin, tinzaparin or dalteparin. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Clexane Syringes if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have a history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high levels of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section 2, ‘Other medicines and Clexane Syringes’)
- you have any problem with your spine or you have had spinal surgery.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Clexane Syringes.

For patients receiving doses higher than 210 mg/day, this medicine contains more than 24 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult.

**Tests and checks**
You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

**Use in children and adolescents**
The safety and efficacy of Clexane Syringes has not been evaluated in children or adolescents.

**Other medicines and Clexane Syringes**
Tell your doctor or pharmacist if you are taking or might take any other medicines.
- warfarin – used for thinning the blood
- aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see section 3, ‘Changing anticoagulant medicine’)
- dextran injection – used as a blood replacer
- ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory medicines which are used to treat pain and swelling in arthritis and other conditions
- prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- medicines which increase potassium levels in your blood such as potassium salts, water pills, and some medicines for heart problems.

**Operations and anaesthetics**

If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Clexane Syringes.

**Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

**Driving and using machines**

Clexane Syringes do not affect the ability to drive and operate machinery.

It is advised that the trade name and batch number of the product you are using are recorded by your healthcare professional.

## 3 How to use Clexane Syringes

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- Your doctor or nurse will normally give you Clexane Syringes. This is because they need to be given as an injection.
- Clexane Syringes are usually given by injection underneath the skin (subcutaneous).
- Clexane Syringes can be given by injection into your vein (intravenous) after certain types of heart attack or operations.
- Clexane Syringes can be added to the tube leaving the body (arterial line) at the start of a dialysis session.
- Do not inject Clexane Syringes into a muscle.

**How much will be given to you**

- Your doctor will decide how much Clexane Syringes to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Clexane Syringes.

**1) Treating blood clots that are in your blood**

- The usual dose is 150 IU (1.5 mg) for every kilogram of your bodyweight once a day or 100 IU (1 mg) for every kilogram of your bodyweight twice a day.
- Your doctor will decide how long you should receive Clexane Syringes.

**2) Stopping blood clots from forming in your blood during operations or periods of limited mobility due to an illness**

- The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Clexane Syringes each day.
- If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Clexane Syringes each day.
- Your doctor will decide how long you should receive Clexane Syringes.

**3) Stopping blood clots when you have unstable angina or after you have had a heart attack**

- Clexane Syringes can be used for two different types of heart attack.
- The amount of Clexane Syringes given to you will depend on your age and the kind of heart attack you have had.

NSTEMI (Non-ST segment Elevation Myocardial Infarction) type of heart attack:
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Clexane Syringes.



STEMI (ST segment Elevation Myocardial Infarction) type of heart attack if you are under 75 years old:
- An initial dose of 3,000 IU (30 mg) of Clexane Syringes will be given as an injection into your vein.
- At the same time you will also be given Clexane Syringes as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Clexane Syringes.

STEMI type of heart attack if you are 75 years old or older:
- The usual dose is 75 IU (0.75 mg) for every kilogram of your bodyweight, every 12 hours.
- The maximum amount of Clexane Syringes given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Clexane Syringes.

For patients that have an operation called percutaneous coronary intervention (PCI):
- Depending on when you were last given Clexane Syringes, your doctor may decide to give an additional dose of Clexane Syringes before a PCI operation.
  This is by injection into your vein.

**4) Stopping blood clots from forming in the tubes of your dialysis machine**

- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.
- Clexane Syringes are added to the tube leaving the body (arterial line) at the start of a dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a futher dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your bodyweight, if necessary.

**Giving yourself an injection of Clexane Syringes**

If you are able to give Clexane Syringes to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately. Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

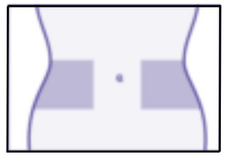
**Before injecting yourself with Clexane Syringes**

- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container
- Check the expiry date on the medicine. Do not use if the date has passed
- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe
- Make sure you know how much you are going to inject
- Check your stomach to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so talk to your doctor or nurse

**Instructions on injecting yourself with Clexane Syringes:**

**Preparing the injection site**

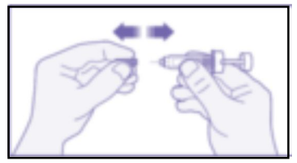
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
- Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
- Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

**Selecting your dose**

1) Carefully pull off the needle cap from the syringe. Throw away the cap.
- Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
- Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

**Injecting**

1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
   - Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.

3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out. You can now let go of the skin fold.

**When you have finished**

1) To avoid bruising, do not rub the injection site after you have injected yourself.

2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

**Changing anticoagulant medicine**

- **Changing from Clexane Syringes to blood thinners called vitamin-K antagonists (such as warfarin)**
  Your doctor will ask you to have blood tests called INR and tell you when to stop Clexane Syringes.

- **Changing from blood thinners called vitamin-K antagonists (such as warfarin) to Clexane Syringes** Stop taking the vitamin-K antagonist.
  Your doctor will ask you to have blood tests called INR and tell you when to start Clexane Syringes.

- **Changing from Clexane Syringes to treatment with direct oral anticoagulants**
  Stop taking Clexane Syringes. Start taking the direct oral anticoagulant 0 to 2 hours before the time you would have had the next injection, then continue as normal.`

- **Changing from treatment with direct oral anticoagulants to Clexane Syringes**
  Stop taking the direct oral anticoagulant. Do not start treatment with Clexane Syringes until 12 hours after the final dose of the direct oral anticoagulant.

**If you use more Clexane Syringes than you should**

If you think that you have used too much or too little Clexane Syringes, tell your doctor or pharmacist or nurse immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Clexane Syringes, take them to a hospital casualty department straight away.

**If you forget to use Clexane Syringes**

If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

**If you stop using Clexane Syringes**

It is important for you to keep having Clexane Syringes injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

**Stop using Clexane Syringes and talk to a doctor or nurse straight away** if you get any signs of a severe allergic reaction (such as rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes).

**Stop using Clexane Syringes and seek medical attention immediately if you notice any of the following symptoms:**
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

Like other similar medicines to reduce blood clotting, Clexane Syringes may cause bleeding . This may be life-threatening. In some cases the bleeding may not be obvious.

**Talk to your doctor straight away if:**
- you have any bleeding that does not stop by itself
- you have signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling

Your doctor may decide to keep you under closer observation or change your medicine.

**You should tell your doctor straight away:**
- if you have any sign of blockage of a blood vessel by a blood clot such as:
  - cramping pain, redness, warmth, or swelling in one of your legs
    – these are symptoms of deep vein thrombosis
  - breathlessness, chest pain, fainting or coughing up blood
    – these are symptoms of a pulmonary embolism
- if you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may request you perform a blood test to check your platelet count.



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**Other side effects**

**Very common** (may affect more than 1 in 10 people):
- Bleeding
- Increases in liver enzymes

**Common** (may affect up to 1 in 10 people):
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts
- pink patches on your skin – these are more likely to appear in the area you have been injected with Lovenox Syringes
- skin rash (hives, urticaria)
- itchy red skin
- bruising or pain at the injection site
- decreased red blood cell count
- high platelet counts in the blood
- headache

**Uncommon** (may affect up to 1 in 100 people):
- sudden severe headache – this could be a sign of bleeding in the brain
- a feeling of tenderness and swelling in your stomach – you may have bleeding in your stomach
- large red irregularly shaped skin lesions with or without blisters
- skin irritation (local irritation)
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem

**Rare** (may affect up to 1 in 1,000 people):
- severe allergic reaction – the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- increased potassium in your blood – this is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test
- an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- hair loss
- osteoporosis (a condition where your bones are more likely to break) after long term use
- tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic
- loss of control over your bladder or bowel (so you cannot control when you go to the toilet)
- hard mass or lump at the injection site.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Lovenox Syringes

Do not use this medicine after the expiry date shown on the carton or syringe blister container. The expiry date refers to the last day of that month. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine, if your doctor tells you to.
If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Do not take the syringe out of the box until you need to use it.

Do not use this medicine if you notice a breach in the syringe, particulate matters in the solution, or an abnormal colour of the solution (see "What Lovenox Syringes look like and the contents of the pack").

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.



## 6 Contents of the pack and other information

**What Lovenox Syringes contains**
The active substance is enoxaparin sodium
Each mL contains 100mg enoxaparin sodium, equivalent to 10,000 IU of anti-Xa activity
Each pre-filled syringe of 0.2mL contains 2,000 IU (20mg) of enoxaparin sodium
Each pre-filled syringe of 0.4mL contains 4,000 IU (40mg) of enoxaparin sodium
Each pre-filled syringe of 0.6mL contains 6,000 IU (60mg) of enoxaparin sodium
Each pre-filled syringe of 0.8mL contains 8,000 IU (80mg) of enoxaparin sodium
Each pre-filled syringe of 1mL contains 10,000 IU (100mg) of enoxaparin sodium
The other ingredient is water for injections

**What Lovenox Syringes looks like and contents of the pack**
Lovenox Syringes are type 1 glass pre-filled syringes fitted with injection needles. Lovenox Syringes comes in packs of 6 or 10 syringes.

**Product Licence Holder and Manufacturer**
Lovenox Syringes are manufactured by Sanofi-Aventis. S.A Avda. de Leganes, 62, 28925 Alcorcon-Madrid, Spain and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL 15184/0742 Lovenox 2,000IU (20mg)/0.2ml Syringes / Lovenox 4,000IU (40mg)/0.4ml Syringes / Lovenox 6,000IU (60mg)/0.6ml Syringes / Lovenox 8,000IU (80mg)/0.8ml Syringes / Lovenox 10,000IU (100mg)/1ml Syringes

Lovenox is a registered trademark of Sanofi Mature IP

Revision date: 25/08/23

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you

Ref:0742/250823/5/F

# Lovenox® 2,000IU (20mg)/0.2ml Syringes / Lovenox® 4,000IU (40mg)/0.4ml Syringes / Lovenox® 6,000IU (60mg)/0.6ml Syringes / Lovenox® 8,000IU (80mg)/0.8ml Syringes / Lovenox® 10,000IU (100mg)/1ml Syringes

(enoxaparin sodium)

## Patient Information Leaflet

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Lovenox 2,000IU (20mg)/0.2ml Syringes /Lovenox 4,000IU (40mg)/0.4ml Syringes /Lovenox 6,000IU (60mg)/0.6ml Syringes / Lovenox 8,000IU (80mg)/0.8ml Syringes /Lovenox 10,000IU (100mg)/1ml Syringes and will be referred to as Lovenox Syringes throughout the rest of this leaflet.

**What is in this leaflet**


1 What Lovenox Syringes are and what they are used for
2 What you need to know before you use Lovenox Syringes
3 How to use Lovenox Syringes
4 Possible side effects
5 How to store Lovenox Syringes
6 Contents of the pack and other information


## 1 What Lovenox Syringes are and what they are used for

Lovenox Syringes contain the active substance called enoxaparin sodium. This belongs to a group of medicines called 'low molecular weight heparin' or LMWH.

**How Lovenox Syringes work**
Lovenox Syringes work in two ways:
1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm.
2) Stopping new blood clots from forming in your blood.

**What Lovenox Syringes are used for**
Lovenox Syringes can be used to:
- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
  - before and after an operation
  - when you have a short-term illness and will not be able to move around for some time.
  - if you have experienced a blood clot due to cancer to prevent further clots from forming
- Stop blood clots from forming when you have unstable angina (where not enough blood gets to your heart) or after a heart attack
- Stop blood clots from forming in the tubes of your dialysis machine (used for people with severe kidney problems).

## 2 What you need to know before you use Lovenox Syringes

**Do not use Lovenox Syringes if:**
- you are allergic to:
  - enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6)
  - heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin. Signs of an allergic reaction include: rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes.
- you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) within the last 100 days
- you have antibodies against enoxaparin in your blood
- you are bleeding heavily or have a condition with a high risk of bleeding, such as:
  - stomach ulcer, recent surgery of the brain or eyes, or recent bleeding stroke.
- you are using Lovenox Syringes to treat blood clots and are going to have within 24 hours:
  - a spinal or lumbar puncture
  - an operation with epidural or spinal anaesthesia.

Do not use Lovenox Syringes if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Lovenox Syringes.

**Warnings and precautions**
Lovenox Syringes should not be interchanged with other 'low molecular weight heparins' such as nadroparin, tinzaparin or dalteparin. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Lovenox Syringes if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have a history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high levels of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section 2, 'Other medicines and Lovenox Syringes')
- you have any problem with your spine or you have had spinal surgery.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Lovenox Syringes.

For patients receiving doses higher than 210 mg/ day, this medicine contains more than 24 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult.

**Tests and checks**
You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

**Use in children and adolescents**
The safety and efficacy of Lovenox Syringes has not been evaluated in children or adolescents.

**Other medicines and Lovenox Syringes**
Tell your doctor or pharmacist if you are taking or might take any other medicines.
- warfarin – used for thinning the blood
- aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see section 3, 'Changing anticoagulant medicine')
- dextran injection – used as a blood replacer
- ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory medicines which are used to treat pain and swelling in arthritis and other conditions
- prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- medicines which increase potassium levels in your blood such as potassium salts, water pills, and some medicines for heart problems.

**Operations and anaesthetics**

If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Lovenox Syringes.

**Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

**Driving and using machines**

Lovenox Syringes do not affect the ability to drive and operate machinery.

It is advised that the trade name and batch number of the product you are using are recorded by your healthcare professional.

## 3 How to use Lovenox Syringes

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- Your doctor or nurse will normally give you Lovenox Syringes. This is because they need to be given as an injection.
- Lovenox Syringes are usually given by injection underneath the skin (subcutaneous).
- Lovenox Syringes can be given by injection into your vein (intravenous) after certain types of heart attack or operations.
- Lovenox Syringes can be added to the tube leaving the body (arterial line) at the start of a dialysis session.
- Do not inject Lovenox Syringes into a muscle.

**How much will be given to you**

- Your doctor will decide how much Lovenox Syringes to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Lovenox Syringes.

**1) Treating blood clots that are in your blood**

- The usual dose is 150 IU (1.5 mg) for every kilogram of your bodyweight once a day or 100 IU (1 mg) for every kilogram of your bodyweight twice a day.
- Your doctor will decide how long you should receive Lovenox Syringes.

**2) Stopping blood clots from forming in your blood during operations or periods of limited mobility due to an illness**

- The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Lovenox Syringes each day.
- If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Lovenox Syringes each day.
- Your doctor will decide how long you should receive Lovenox Syringes.

**3) Stopping blood clots when you have unstable angina or after you have had a heart attack**

- Lovenox Syringes can be used for two different types of heart attack.
- The amount of Lovenox Syringes given to you will depend on your age and the kind of heart attack you have had.

NSTEMI (Non-ST segment Elevation Myocardial Infarction) type of heart attack:
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Lovenox Syringes.



STEMI (ST segment Elevation Myocardial Infarction) type of heart attack if you are under 75 years old:
- An initial dose of 3,000 IU (30 mg) of Lovenox Syringes will be given as an injection into your vein.
- At the same time you will also be given Lovenox Syringes as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Lovenox Syringes.

STEMI type of heart attack if you are 75 years old or older:
- The usual dose is 75 IU (0.75 mg) for every kilogram of your bodyweight, every 12 hours.
- The maximum amount of Lovenox Syringes given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Lovenox Syringes.

For patients that have an operation called percutaneous coronary intervention (PCI):
- Depending on when you were last given Lovenox Syringes, your doctor may decide to give an additional dose of Lovenox Syringes before a PCI operation.
  This is by injection into your vein.

**4) Stopping blood clots from forming in the tubes of your dialysis machine**
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.
- Lovenox Syringes are added to the tube leaving the body (arterial line) at the start of a dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a futher dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your bodyweight, if necessary.

**Giving yourself an injection of Lovenox Syringes**

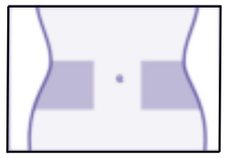
If you are able to give Lovenox Syringes to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately. Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

**Before injecting yourself with Lovenox Syringes**

- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container
- Check the expiry date on the medicine. Do not use if the date has passed
- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe
- Make sure you know how much you are going to inject
- Check your stomach to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so talk to your doctor or nurse

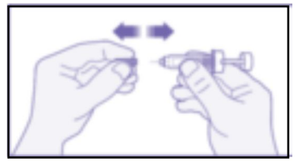
**Instructions on injecting yourself with Lovenox Syringes:**

**Preparing the injection site**
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
- Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
- Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

**Selecting your dose**
1) Carefully pull off the needle cap from the syringe. Throw away the cap.
- Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
- Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

**Injecting**

1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
   - Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.

3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out. You can now let go of the skin fold.

**When you have finished**

1) To avoid bruising, do not rub the injection site after you have injected yourself.

2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

**Changing anticoagulant medicine**

- **Changing from Lovenox Syringes to blood thinners called vitamin-K antagonists (such as warfarin)**
  Your doctor will ask you to have blood tests called INR and tell you when to stop Lovenox Syringes.

- **Changing from blood thinners called vitamin-K antagonists (such as warfarin) to Lovenox Syringes**
  Stop taking the vitamin-K antagonist.
  Your doctor will ask you to have blood tests called INR and tell you when to start Lovenox Syringes.

- **Changing from Lovenox Syringes to treatment with direct oral anticoagulants**
  Stop taking Lovenox Syringes. Start taking the direct oral anticoagulant 0 to 2 hours before the time you would have had the next injection, then continue as normal.

- **Changing from treatment with direct oral anticoagulants to Lovenox Syringes**
  Stop taking the direct oral anticoagulant. Do not start treatment with Lovenox Syringes until 12 hours after the final dose of the direct oral anticoagulant.

**If you use more Lovenox Syringes than you should**

If you think that you have used too much or too little Lovenox Syringes, tell your doctor or pharmacist or nurse immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Lovenox Syringes, take them to a hospital casualty department straight away.

**If you forget to use Lovenox Syringes**

If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

**If you stop using Lovenox Syringes**

It is important for you to keep having Lovenox Syringes injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

**Stop using Lovenox Syringes and talk to a doctor or nurse straight away** if you get any signs of a severe allergic reaction (such as rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes).

**Stop using Lovenox Syringes and seek medical attention immediately if you notice any of the following symptoms:**
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

Like other similar medicines to reduce blood clotting, Lovenox Syringes may cause bleeding . This may be life-threatening. In some cases the bleeding may not be obvious.

**Talk to your doctor straight away if:**
- you have any bleeding that does not stop by itself
- you have signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling

Your doctor may decide to keep you under closer observation or change your medicine.

**You should tell your doctor straight away:**

- if you have any sign of blockage of a blood vessel by a blood clot such as:
  - cramping pain, redness, warmth, or swelling in one of your legs – these are symptoms of deep vein thrombosis
  - breathlessness, chest pain, fainting or coughing up blood – these are symptoms of a pulmonary embolism
- if you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may request you perform a blood test to check your platelet count.



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**Other side effects**

**Very common** (may affect more than 1 in 10 people):
- Bleeding
- Increases in liver enzymes

**Common** (may affect up to 1 in 10 people):
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts
- pink patches on your skin – these are more likely to appear in the area you have been injected with Clexane Syringes
- skin rash (hives, urticaria)
- itchy red skin
- bruising or pain at the injection site
- decreased red blood cell count
- high platelet counts in the blood
- headache

**Uncommon** (may affect up to 1 in 100 people):
- sudden severe headache – this could be a sign of bleeding in the brain
- a feeling of tenderness and swelling in your stomach – you may have bleeding in your stomach
- large red irregularly shaped skin lesions with or without blisters
- skin irritation (local irritation)
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem

**Rare** (may affect up to 1 in 1,000 people):
- severe allergic reaction – the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- increased potassium in your blood – this is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test
- an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- hair loss
- osteoporosis (a condition where your bones are more likely to break) after long term use
- tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic
- loss of control over your bladder or bowel (so you cannot control when you go to the toilet)
- hard mass or lump at the injection site.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Clexane Syringes

Do not use this medicine after the expiry date shown on the carton or syringe blister container. The expiry date refers to the last day of that month. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine, if your doctor tells you to.
If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Do not take the syringe out of the box until you need to use it.

Do not use this medicine if you notice a breach in the syringe, particulate matters in the solution, or an abnormal colour of the solution (see “What Clexane Syringes look like and the contents of the pack”).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.



## 6 Contents of the pack and other information

**What Clexane Syringes contains**
The active substance is enoxaparin sodium
Each mL contains 100mg enoxaparin sodium, equivalent to 10,000 IU of anti-Xa activity
Each pre-filled syringe of 0.2mL contains 2,000IU (20mg) of enoxaparin sodium
Each pre-filled syringe of 0.4mL contains 4,000IU (40mg) of enoxaparin sodium
Each pre-filled syringe of 0.6mL contains 6,000IU (60mg) of enoxaparin sodium
Each pre-filled syringe of 0.8mL contains 8,000IU (80mg) of enoxaparin sodium
Each pre-filled syringe of 1mL contains 10,000IU (100mg) of enoxaparin sodium
The other ingredient is water for injections

**What Clexane Syringes looks like and contents of the pack**
Clexane Syringes are type 1 glass pre-filled syringes fitted with injection needles. Clexane  Syringes comes in packs of 6 or 10 syringes.

**Product Licence Holder and Manufacturer**
Clexane Syringes are manufactured by Sanofi Winthrop Industrie, Boulevard Industriel, Zone Industrielle 76580 Le Trait, France  and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

**POM** PL 15184/0742 Clexane 2,000IU (20mg)/0.2ml Syringes / Clexane 4,000IU (40mg)/0.4ml Syringes / Clexane 6,000IU (60mg)/0.6ml Syringes / Clexane 8,000IU (80mg)/0.8ml Syringes / Clexane 10,000IU (100mg)/1ml Syringes

Clexane Syringes is a registered trademark of Sanofi Mature IP

Revision date: 25/08/23

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you

Ref:0742/250823/7/F

# Clexane® 2,000IU (20mg)/0.2ml Syringes / Clexane® 4,000IU (40mg)/0.4ml Syringes / Clexane® 6,000IU (60mg)/0.6ml Syringes / Clexane® 8,000IU (80mg)/0.8ml Syringes / Clexane® 10,000IU (100mg)/1ml Syringes

(enoxaparin sodium)

## Patient Information Leaflet

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Clexane 2,000IU (20mg)/0.2ml Syringes, Clexane 4,000IU (40mg)/0.4ml Syringes / Clexane 6,000IU (60mg)/0.6ml Syringes/ Clexane 8,000IU (80mg)/0.8ml Syringes / Clexane 10,000IU (100mg)/1ml Syringes and will be referred to as Clexane Syringes throughout the rest of this leaflet.

**What is in this leaflet**

1 What Clexane Syringes are and what they are used for
2 What you need to know before you use Clexane Syringes
3 How to use Clexane Syringes
4 Possible side effects
5 How to store Clexane Syringes
6 Contents of the pack and other information


## 1 What Clexane Syringes are and what they are used for

Clexane Syringes contain the active substance called enoxaparin sodium. This belongs to a group of medicines called ‘low molecular weight heparin’ or LMWH.

**How Clexane Syringes work**
Clexane Syringes work in two ways:
1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm.
2) Stopping new blood clots from forming in your blood.

**What Clexane Syringes are used for**
Clexane Syringes can be used to:
- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
  - before and after an operation
  - when you have a short-term illness and will not be able to move around for some time.
  - if you have experienced a blood clot due to cancer to prevent further clots from forming
- Stop blood clots from forming when you have unstable angina (where not enough blood gets to your heart) or after a heart attack
- Stop blood clots from forming in the tubes of your dialysis machine (used for people with severe kidney problems).

## 2 What you need to know before you use Clexane Syringes

**Do not use Clexane Syringes if:**
- you are allergic to:
  - enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6)
  - heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin. Signs of an allergic reaction include: rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes.
- you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) within the last 100 days
- you have antibodies against enoxaparin in your blood
- you are bleeding heavily or have a condition with a high risk of bleeding, such as:
  - stomach ulcer, recent surgery of the brain or eyes, or recent bleeding stroke.
- you are using Clexane Syringes to treat blood clots and are going to have within 24 hours:
  - a spinal or lumbar puncture
  - an operation with epidural or spinal anaesthesia.

Do not use Clexane Syringes if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Clexane Syringes.

**Warnings and precautions**
Clexane Syringes should not be interchanged with other ‘low molecular weight heparins’ such as nadroparin, tinzaparin or dalteparin. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Clexane Syringes if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have a history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high levels of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section 2, ‘Other medicines and Clexane Syringes’)
- you have any problem with your spine or you have had spinal surgery.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Clexane Syringes.

For patients receiving doses higher than 210 mg/day, this medicine contains more than 24 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult.

**Tests and checks**
You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

**Use in children and adolescents**
The safety and efficacy of Clexane Syringes has not been evaluated in children or adolescents.

**Other medicines and Clexane Syringes**
Tell your doctor or pharmacist if you are taking or might take any other medicines.
- warfarin – used for thinning the blood
- aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see section 3, ‘Changing anticoagulant medicine’)
- dextran injection – used as a blood replacer
- ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory medicines which are used to treat pain and swelling in arthritis and other conditions
- prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- medicines which increase potassium levels in your blood such as potassium salts, water pills, and some medicines for heart problems.

**Operations and anaesthetics**
If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Clexane Syringes.

**Pregnancy and breast-feeding**
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

**Driving and using machines**
Clexane Syringes do not affect the ability to drive and operate machinery.

It is advised that the trade name and batch number of the product you are using are recorded by your healthcare professional.

## 3 How to use Clexane Syringes

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Having this medicine**
- Your doctor or nurse will normally give you Clexane Syringes. This is because they need to be given as an injection.
- Clexane Syringes are usually given by injection underneath the skin (subcutaneous).
- Clexane Syringes can be given by injection into your vein (intravenous) after certain types of heart attack or operations.
- Clexane Syringes can be added to the tube leaving the body (arterial line) at the start of a dialysis session.
- Do not inject Clexane Syringes into a muscle.

**How much will be given to you**
- Your doctor will decide how much Clexane Syringes to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Clexane Syringes.

**1) Treating blood clots that are in your blood**
- The usual dose is 150 IU (1.5 mg) for every kilogram of your bodyweight once a day or 100 IU (1 mg) for every kilogram of your bodyweight twice a day.
- Your doctor will decide how long you should receive Clexane Syringes.

**2) Stopping blood clots from forming in your blood during operations or periods of limited mobility due to an illness**
- The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Clexane Syringes each day.
- If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Clexane Syringes each day.
- Your doctor will decide how long you should receive Clexane Syringes.

**3) Stopping blood clots when you have unstable angina or after you have had a heart attack**
- Clexane Syringes can be used for two different types of heart attack.
- The amount of Clexane Syringes given to you will depend on your age and the kind of heart attack you have had.

NSTEMI (Non-ST segment Elevation Myocardial Infarction) type of heart attack:
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Clexane Syringes.



STEMI (ST segment Elevation Myocardial Infarction) type of heart attack if you are under 75 years old:
- An initial dose of 3,000 IU (30 mg) of Clexane Syringes will be given as an injection into your vein.
- At the same time you will also be given Clexane Syringes as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Clexane Syringes.

STEMI type of heart attack if you are 75 years old or older:
- The usual dose is 75 IU (0.75 mg) for every kilogram of your bodyweight, every 12 hours.
- The maximum amount of Clexane Syringes given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Clexane Syringes.

For patients that have an operation called percutaneous coronary intervention (PCI):
- Depending on when you were last given Clexane Syringes, your doctor may decide to give an additional dose of Clexane Syringes before a PCI operation. This is by injection into your vein.

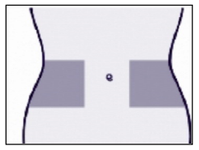
**4) Stopping blood clots from forming in the tubes of your dialysis machine**
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.
- Clexane Syringes are added to the tube leaving the body (arterial line) at the start of a dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a futher dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your bodyweight, if necessary.

**Giving yourself an injection of Clexane Syringes**
If you are able to give Clexane Syringes to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately. Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

**Before injecting yourself with Clexane Syringes**
- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container
- Check the expiry date on the medicine. Do not use if the date has passed
- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe
- Make sure you know how much you are going to inject
- Check your stomach to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so talk to your doctor or nurse

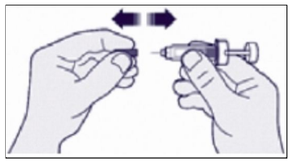
**Instructions on injecting yourself with Clexane Syringes:**

**Preparing the injection site**
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
- Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
- Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

**Selecting your dose**
1) Carefully pull off the needle cap from the syringe. Throw away the cap.
- Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
- Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

**Injecting**
1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
   - Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.




3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out. You can now let go of the skin fold.

**When you have finished**
1) To avoid bruising, do not rub the injection site after you have injected yourself.
2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

**Changing anticoagulant medicine**

- **Changing from Clexane Syringes to blood thinners called vitamin-K antagonists (such as warfarin)**
  Your doctor will ask you to have blood tests called INR and tell you when to stop Clexane Syringes.

- **Changing from blood thinners called vitamin-K antagonists (such as warfarin) to Clexane Syringes**
  Stop taking the vitamin-K antagonist.
  Your doctor will ask you to have blood tests called INR and tell you when to start Clexane Syringes.

- **Changing from Clexane Syringes to treatment with direct oral anticoagulants**
  Stop taking Clexane Syringes. Start taking the direct oral anticoagulant 0 to 2 hours before the time you would have had the next injection, then continue as normal.

- **Changing from treatment with direct oral anticoagulants to Clexane Syringes**
  Stop taking the direct oral anticoagulant. Do not start treatment with Clexane Syringes until 12 hours after the final dose of the direct oral anticoagulant.

**If you use more Clexane Syringes than you should**
If you think that you have used too much or too little Clexane Syringes, tell your doctor or pharmacist or nurse immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Clexane Syringes, take them to a hospital casualty department straight away.

**If you forget to use Clexane Syringes**
If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

**If you stop using Clexane Syringes**
It is important for you to keep having Clexane Syringes injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

**Stop using Clexane Syringes and talk to a doctor or nurse straight away** if you get any signs of a severe allergic reaction (such as rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes).

**Stop using Clexane Syringes and seek medical attention immediately if you notice any of the following symptoms:**
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

Like other similar medicines to reduce blood clotting, Clexane Syringes may cause bleeding . This may be life-threatening. In some cases the bleeding may not be obvious.

**Talk to your doctor straight away if:**
- you have any bleeding that does not stop by itself
- you have signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling

Your doctor may decide to keep you under closer observation or change your medicine.

**You should tell your doctor straight away:**
- if you have any sign of blockage of a blood vessel by a blood clot such as:
  - cramping pain, redness, warmth, or swelling in one of your legs – these are symptoms of deep vein thrombosis
  - breathlessness, chest pain, fainting or coughing up blood – these are symptoms of a pulmonary embolism
- if you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may request you perform a blood test to check your platelet count.



Ref:0742/250823/7/B

**Other side effects**

**Very common** (may affect more than 1 in 10 people):
- Bleeding
- Increases in liver enzymes

**Common** (may affect up to 1 in 10 people):
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts
- pink patches on your skin – these are more likely to appear in the area you have been injected with Lovenox Syringes
- skin rash (hives, urticaria)
- itchy red skin
- bruising or pain at the injection site
- decreased red blood cell count
- high platelet counts in the blood
- headache

**Uncommon** (may affect up to 1 in 100 people):
- sudden severe headache – this could be a sign of bleeding in the brain
- a feeling of tenderness and swelling in your stomach – you may have bleeding in your stomach
- large red irregularly shaped skin lesions with or without blisters
- skin irritation (local irritation)
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem

**Rare** (may affect up to 1 in 1,000 people):
- severe allergic reaction – the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- increased potassium in your blood – this is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test
- an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- hair loss
- osteoporosis (a condition where your bones are more likely to break) after long term use
- tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic
- loss of control over your bladder or bowel (so you cannot control when you go to the toilet)
- hard mass or lump at the injection site.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Lovenox Syringes

Do not use this medicine after the expiry date shown on the carton or syringe blister container. The expiry date refers to the last day of that month. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine, if your doctor tells you to.
If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Do not take the syringe out of the box until you need to use it.

Do not use this medicine if you notice a breach in the syringe, particulate matters in the solution, or an abnormal colour of the solution (see "What Lovenox Syringes look like and the contents of the pack").

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.



## 6 Contents of the pack and other information

**What Lovenox Syringes contains**
The active substance is enoxaparin sodium
Each mL contains 100mg enoxaparin sodium, equivalent to 10,000 IU of anti-Xa activity
Each pre-filled syringe of 0.2mL contains 2,000 IU (20mg) of enoxaparin sodium
Each pre-filled syringe of 0.4mL contains 4,000 IU (40mg) of enoxaparin sodium
Each pre-filled syringe of 0.6mL contains 6,000 IU (60mg) of enoxaparin sodium
Each pre-filled syringe of 0.8mL contains 8,000 IU (80mg) of enoxaparin sodium
Each pre-filled syringe of 1mL contains 10,000 IU (100mg) of enoxaparin sodium
The other ingredient is water for injections

**What Lovenox Syringes looks like and contents of the pack**
Lovenox Syringes are type 1 glass pre-filled syringes fitted with injection needles. Lovenox Syringes comes in packs of 6 or 10 syringes.

**Product Licence Holder and Manufacturer**
Lovenox Syringes are manufactured by Sanofi Winthrop Industrie, 180 rue Jean Jaures, 94700 Maisons-Alfort, France and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

POM PL 15184/0742 Lovenox 2,000IU (20mg)/0.2ml Syringes / Lovenox 4,000IU (40mg)/0.4ml Syringes / Lovenox 6,000IU (60mg)/0.6ml Syringes / Lovenox 8,000IU (80mg)/0.8ml Syringes / Lovenox 10,000IU (100mg)/1ml Syringes

Lovenox Syringes is a registered trademark of Sanofi Mature IP.

Revision date: 19/03/25

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Tel: 01527 505414 to obtain the leaflet in a format suitable for you

amend at print to
Sanofi Winthrop Industrie,
Boulevard
Industriel, Zone Industrielle
76580 Le Trait, France

Ref:0742/190325/8/F

# Lovenox® 2,000IU (200mg)/0.2ml Syringes / Lovenox® 4,000IU (40mg)/0.4ml Syringes / Lovenox® 6,000IU (60mg)/0.6ml Syringes / Lovenox® 8,000IU (80mg)/0.8ml Syringes / Lovenox® 10,000IU (100mg)/1ml Syringes

(enoxaparin sodium)

## Patient Information Leaflet

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- s, talk to your doctor or pharmacist. This includes not listed in this leaflet. See section 4.

ovenox 2,000IU (20mg)/0.2ml Syringes /Lovenox nges /Lovenox 6,000IU (60mg)/0.6ml Syringes / .8ml Syringes /Lovenox 10,000IU (100mg)/1ml Syringes and will be referred to as Lovenox Syringes throughout the rest of this leaflet.

**What is in this leaflet**

1 What Lovenox Syringes are and what they are used for
2 What you need to know before you use Lovenox Syringes
3 How to use Lovenox Syringes
4 Possible side effects
5 How to store Lovenox Syringes
6 Contents of the pack and other information


## 1 What Lovenox Syringes are and what they are used for

Lovenox Syringes contain the active substance called enoxaparin sodium. This belongs to a group of medicines called 'low molecular weight heparin' or LMWH.

**How Lovenox Syringes work**
Lovenox Syringes work in two ways:
1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm.
2) Stopping new blood clots from forming in your blood.

**What Lovenox Syringes are used for**
Lovenox Syringes can be used to:
- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
  - before and after an operation
  - when you have a short-term illness and will not be able to move around for some time.
  - if you have experienced a blood clot due to cancer to prevent further clots from forming
- Stop blood clots from forming when you have unstable angina (where not enough blood gets to your heart) or after a heart attack
- Stop blood clots from forming in the tubes of your dialysis machine (used for people with severe kidney problems).

## 2 What you need to know before you use Lovenox Syringes

**Do not use Lovenox Syringes if:**
- you are allergic to:
  - enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6)
  - heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin. Signs of an allergic reaction include: rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes.
- you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) within the last 100 days
- you have antibodies against enoxaparin in your blood
- you are bleeding heavily or have a condition with a high risk of bleeding, such as:
  - stomach ulcer, recent surgery of the brain or eyes, or recent bleeding stroke.
- you are using Lovenox Syringes to treat blood clots and are going to have within 24 hours:
  - a spinal or lumbar puncture
  - an operation with epidural or spinal anaesthesia.

Do not use Lovenox Syringes if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Lovenox Syringes.

**Warnings and precautions**
Lovenox Syringes should not be interchanged with other 'low molecular weight heparins' such as nadroparin, tinzaparin or dalteparin. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Lovenox Syringes if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have a history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high levels of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section 2, 'Other medicines and Lovenox Syringes')
- you have any problem with your spine or you have had spinal surgery.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Lovenox Syringes.

For patients receiving doses higher than 210 mg/day, this medicine contains more than 24 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult.

**Tests and checks**
You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

**Use in children and adolescents**
The safety and efficacy of Lovenox Syringes has not been evaluated in children or adolescents.

**Other medicines and Lovenox Syringes**
Tell your doctor or pharmacist if you are taking or might take any other medicines.
- warfarin – used for thinning the blood
- aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see section 3, 'Changing anticoagulant medicine')
- dextran injection – used as a blood replacer
- ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory medicines which are used to treat pain and swelling in arthritis and other conditions
- prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- medicines which increase potassium levels in your blood such as potassium salts, water pills, and some medicines for heart problems.

**Operations and anaesthetics**

If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Lovenox Syringes.

**Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

**Driving and using machines**

Lovenox Syringes do not affect the ability to drive and operate machinery.

It is advised that the trade name and batch number of the product you are using are recorded by your healthcare professional.

## 3 How to use Lovenox Syringes

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- Your doctor or nurse will normally give you Lovenox Syringes. This is because they need to be given as an injection.
- Lovenox Syringes are usually given by injection underneath the skin (subcutaneous).
- Lovenox Syringes can be given by injection into your vein (intravenous) after certain types of heart attack or operations.
- Lovenox Syringes can be added to the tube leaving the body (arterial line) at the start of a dialysis session.
- Do not inject Lovenox Syringes into a muscle.

**How much will be given to you**

- Your doctor will decide how much Lovenox Syringes to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Lovenox Syringes.

**1) Treating blood clots that are in your blood**

- The usual dose is 150 IU (1.5 mg) for every kilogram of your bodyweight once a day or 100 IU (1 mg) for every kilogram of your bodyweight twice a day.
- Your doctor will decide how long you should receive Lovenox Syringes.

**2) Stopping blood clots from forming in your blood during operations or periods of limited mobility due to an illness**

- The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Lovenox Syringes each day.
- If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Lovenox Syringes each day.
- Your doctor will decide how long you should receive Lovenox Syringes.

**3) Stopping blood clots when you have unstable angina or after you have had a heart attack**

- Lovenox Syringes can be used for two different types of heart attack.
- The amount of Lovenox Syringes given to you will depend on your age and the kind of heart attack you have had.

NSTEMI (Non-ST segment Elevation Myocardial Infarction) type of heart attack:
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Lovenox Syringes.



STEMI (ST segment Elevation Myocardial Infarction) type of heart attack if you are under 75 years old:
- An initial dose of 3,000 IU (30 mg) of Lovenox Syringes will be given as an injection into your vein.
- At the same time you will also be given Lovenox Syringes as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Lovenox Syringes.

STEMI type of heart attack if you are 75 years old or older:
- The usual dose is 75 IU (0.75 mg) for every kilogram of your bodyweight, every 12 hours.
- The maximum amount of Lovenox Syringes given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Lovenox Syringes.

For patients that have an operation called percutaneous coronary intervention (PCI):
- Depending on when you were last given Lovenox Syringes, your doctor may decide to give an additional dose of Lovenox Syringes before a PCI operation.
  This is by injection into your vein.

**4) Stopping blood clots from forming in the tubes of your dialysis machine**

- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.
- Lovenox Syringes are added to the tube leaving the body (arterial line) at the start of a dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a futher dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your bodyweight, if necessary.

**Giving yourself an injection of Lovenox Syringes**

If you are able to give Lovenox Syringes to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately. Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

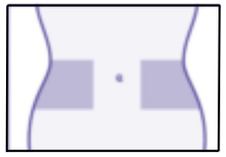
**Before injecting yourself with Lovenox Syringes**

- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container
- Check the expiry date on the medicine. Do not use if the date has passed
- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe
- Make sure you know how much you are going to inject
- Check your stomach to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so talk to your doctor or nurse

**Instructions on injecting yourself with Lovenox Syringes:**

**Preparing the injection site**

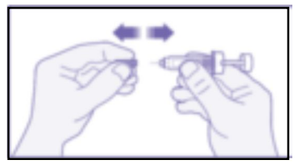
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
- Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
- Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

**Selecting your dose**

1) Carefully pull off the needle cap from the syringe. Throw away the cap.
- Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
- Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

**Injecting**

1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
   - Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.

3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out. You can now let go of the skin fold.

**When you have finished**

1) To avoid bruising, do not rub the injection site after you have injected yourself.

2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

**Changing anticoagulant medicine**

- **Changing from Lovenox Syringes to blood thinners called vitamin-K antagonists (such as warfarin)**
  Your doctor will ask you to have blood tests called INR and tell you when to stop Lovenox Syringes.

- **Changing from blood thinners called vitamin-K antagonists (such as warfarin) to Lovenox Syringes**
  Stop taking the vitamin-K antagonist. Your doctor will ask you to have blood tests called INR and tell you when to start Lovenox Syringes.

- **Changing from Lovenox Syringes to treatment with direct oral anticoagulants**
  Stop taking Lovenox Syringes. Start taking the direct oral anticoagulant 0 to 2 hours before the time you would have had the next injection, then continue as normal.

- **Changing from treatment with direct oral anticoagulants to Lovenox Syringes**
  Stop taking the direct oral anticoagulant. Do not start treatment with Lovenox Syringes until 12 hours after the final dose of the direct oral anticoagulant.

**If you use more Lovenox Syringes than you should**

If you think that you have used too much or too little Lovenox Syringes, tell your doctor or pharmacist or nurse immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Lovenox Syringes, take them to a hospital casualty department straight away.

**If you forget to use Lovenox Syringes**

If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

**If you stop using Lovenox Syringes**

It is important for you to keep having Lovenox Syringes injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

**Stop using Lovenox Syringes and talk to a doctor or nurse straight away** if you get any signs of a severe allergic reaction (such as rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes).

**Stop using Lovenox Syringes and seek medical attention immediately if you notice any of the following symptoms:**
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

Like other similar medicines to reduce blood clotting, Lovenox Syringes may cause bleeding . This may be life-threatening. In some cases the bleeding may not be obvious.

**Talk to your doctor straight away if:**
- you have any bleeding that does not stop by itself
- you have signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling

Your doctor may decide to keep you under closer observation or change your medicine.

**You should tell your doctor straight away:**

- if you have any sign of blockage of a blood vessel by a blood clot such as:
  - cramping pain, redness, warmth, or swelling in one of your legs
    – these are symptoms of deep vein thrombosis
  - breathlessness, chest pain, fainting or coughing up blood
    – these are symptoms of a pulmonary embolism
- if you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may request you perform a blood test to check your platelet count.



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**Other side effects**

**Very common** (may affect more than 1 in 10 people):
- Bleeding
- Increases in liver enzymes

**Common** (may affect up to 1 in 10 people):
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts
- pink patches on your skin – these are more likely to appear in the area you have been injected with Clexane Syringes
- skin rash (hives, urticaria)
- itchy red skin
- bruising or pain at the injection site
- decreased red blood cell count
- high platelet counts in the blood
- headache

**Uncommon** (may affect up to 1 in 100 people):
- sudden severe headache – this could be a sign of bleeding in the brain
- a feeling of tenderness and swelling in your stomach – you may have bleeding in your stomach
- large red irregularly shaped skin lesions with or without blisters
- skin irritation (local irritation)
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem

**Rare** (may affect up to 1 in 1,000 people):
- severe allergic reaction – the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- increased potassium in your blood – this is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test
- an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- hair loss
- osteoporosis (a condition where your bones are more likely to break) after long term use
- tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic
- loss of control over your bladder or bowel (so you cannot control when you go to the toilet)
- hard mass or lump at the injection site.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Clexane Syringes

Do not use this medicine after the expiry date shown on the carton or syringe blister container.The expiry date refers to the last day of that month. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine, if your doctor tells you to.
If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Do not take the syringe out of the box until you need to use it.

Do not use this medicine if you notice a breach in the syringe, particulate matters in the solution, or an abnormal colour of the solution (see "What Clexane Syringes look like and the contents of the pack").

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.



## 6 Contents of the pack and other information

**What Clexane Syringes contains**
Each glass pre-filled syringe contains enoxaparin sodium as the active ingredient.
Clexane Syringes only has water for injection as its other ingredient.
The active substance is enoxaparin sodium
Each mL contains 100mg enoxaparin sodium, equivalent to 10,000 IU of anti-Xa activity
Each pre-filled syringe of 0.2mL contains 2,000 IU (20mg) of enoxaparin sodium
Each pre-filled syringe of 0.4mL contains 4,000 IU (40mg) of enoxaparin sodium
Each pre-filled syringe of 0.6mL contains 6,000 IU (60mg) of enoxaparin sodium
Each pre-filled syringe of 0.8mL contains 8,000 IU (80mg) of enoxaparin sodium
Each pre-filled syringe of 1mL contains 10,000 IU (100mg) of enoxaparin sodium
The other ingredient is water for injections

**What Clexane Syringes looks like and contents of the pack**
Clexane Syringes are type 1 glass pre-filled syringes fitted with injection needles. Clexane Syringes comes in packs of 6 or 10 syringes.

**Product Licence Holder and Manufacturer**
Clexane Syringes are manufactured by Chinoin Pharmaceutical and Chemical Works Private Co.Ltd., Csanyikvolgy, 3510 Miskolc, Hungary and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE

POM PL 15184/0742 Clexane 2,000IU (20mg)/0.2ml Syringes / Clexane 4,000IU (40mg)/0.4ml Syringes / Clexane 6,000IU (60mg)/0.6ml Syringes / Clexane 8,000IU (80mg)/0.8ml Syringes / Clexane 10,000IU (100mg)/1ml Syringes

Clexane Syringes is a registered trademark of Sanofi Mature IP

Revision date: 25/08/23

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Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you

Ref:0742/250823/10/F

# Clexane® 2,000IU (20mg)/0.2ml Syringes / Clexane® 4,000IU (40mg)/0.4ml Syringes / Clexane® 6,000IU (60mg)/0.6ml Syringes / Clexane® 8,000IU (80mg)/0.8ml Syringes / Clexane® 10,000IU (100mg)/1ml Syringes

(enoxaparin sodium)

## Patient Information Leaflet

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Clexane 2,000IU (20mg)/0.2ml Syringes,Clexane 4,000IU (40mg)/0.4ml Syringes / Clexane 6,000IU (60mg)/0.6ml Syringes/ Clexane 8,000IU (80mg)/0.8ml Syringes / Clexane 10,000IU (100mg)/1ml Syringes and will be referred to as Clexane Syringes throughout the rest of this leaflet.

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1 What Clexane Syringes are and what they are used for
2 What you need to know before you use Clexane Syringes
3 How to use Clexane Syringes
4 Possible side effects
5 How to store Clexane Syringes
6 Contents of the pack and other information


## 1 What Clexane Syringes are and what they are used for

Clexane Syringes contain the active substance called enoxaparin sodium. This belongs to a group of medicines called 'low molecular weight heparin' or LMWH.

**How Clexane Syringes work**
Clexane Syringes work in two ways:
1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm.
2) Stopping new blood clots from forming in your blood.

**What Clexane Syringes are used for**
Clexane Syringes can be used to:
- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
  - before and after an operation
  - when you have a short-term illness and will not be able to move around for some time.
  - if you have experienced a blood clot due to cancer to prevent further clots from forming
- Stop blood clots from forming when you have unstable angina (where not enough blood gets to your heart) or after a heart attack
- Stop blood clots from forming in the tubes of your dialysis machine (used for people with severe kidney problems).

## 2 What you need to know before you use Clexane Syringes

**Do not use Clexane Syringes if:**
- you are allergic to:
  - enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6)
  - heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin. Signs of an allergic reaction include: rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes.
- you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) within the last 100 days
- you have antibodies against enoxaparin in your blood
- you are bleeding heavily or have a condition with a high risk of bleeding, such as:
- stomach ulcer, recent surgery of the brain or eyes, or recent bleeding stroke.
- you are using Clexane Syringes to treat blood clots and are going to have within 24 hours:
- a spinal or lumbar puncture
- an operation with epidural or spinal anaesthesia.

Do not use Clexane Syringes if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Clexane Syringes.

**Warnings and precautions**
Clexane Syringes should not be interchanged with other 'low molecular weight heparins' such as nadroparin, tinzaparin or dalteparin. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Clexane Syringes if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have a history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high levels of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section 2, 'Other medicines and Clexane Syringes')
- you have any problem with your spine or you have had spinal surgery.
  If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Clexane Syringes.

For patients receiving doses higher than 210 mg/day, this medicine contains more than 24 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult.

**Tests and checks**
You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

**Use in children and adolescents**
The safety and efficacy of Clexane Syringes has not been evaluated in children or adolescents.

**Other medicines and Clexane Syringes**
Tell your doctor or pharmacist if you are taking or might take any other medicines.
- warfarin – used for thinning the blood
- aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see section 3, 'Changing anticoagulant medicine')
- dextran injection – used as a blood replacer
- ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory medicines which are used to treat pain and swelling in arthritis and other conditions
- prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- medicines which increase potassium levels in your blood such as potassium salts, water pills, and some medicines for heart problems.

**Operations and anaesthetics**

If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Clexane Syringes.

**Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

**Driving and using machines**

Clexane Syringes do not affect the ability to drive and operate machinery.

It is advised that the trade name and batch number of the product you are using are recorded by your healthcare professional.

## 3 How to use Clexane Syringes

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- Your doctor or nurse will normally give you Clexane Syringes. This is because they need to be given as an injection.
- Clexane Syringes are usually given by injection underneath the skin (subcutaneous).
- Clexane Syringes can be given by injection into your vein (intravenous) after certain types of heart attack or operations.
- Clexane Syringes can be added to the tube leaving the body (arterial line) at the start of a dialysis session.
- Do not inject Clexane Syringes into a muscle.

**How much will be given to you**

- Your doctor will decide how much Clexane Syringes to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Clexane Syringes.

**1) Treating blood clots that are in your blood**

- The usual dose is 150 IU (1.5 mg) for every kilogram of your bodyweight once a day or 100 IU (1 mg) for every kilogram of your bodyweight twice a day.
- Your doctor will decide how long you should receive Clexane Syringes.

**2) Stopping blood clots from forming in your blood during operations or periods of limited mobility due to an illness**

- The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Clexane Syringes each day.
- If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Clexane Syringes each day.
- Your doctor will decide how long you should receive Clexane Syringes.

**3) Stopping blood clots when you have unstable angina or after you have had a heart attack**

- Clexane Syringes can be used for two different types of heart attack.
- The amount of Clexane Syringes given to you will depend on your age and the kind of heart attack you have had.

NSTEMI (Non-ST segment Elevation Myocardial Infarction) type of heart attack:
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Clexane Syringes.



STEMI (ST segment Elevation Myocardial Infarction) type of heart attack if you are under 75 years old:
- An initial dose of 3,000 IU (30 mg) of Clexane Syringes will be given as an injection into your vein.
- At the same time you will also be given Clexane Syringes as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Clexane Syringes.

STEMI type of heart attack if you are 75 years old or older:
- The usual dose is 75 IU (0.75 mg) for every kilogram of your bodyweight, every 12 hours.
- The maximum amount of Clexane Syringes given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Clexane Syringes.

For patients that have an operation called percutaneous coronary intervention (PCI):
- Depending on when you were last given Clexane Syringes, your doctor may decide to give an additional dose of Clexane Syringes before a PCI operation.
  This is by injection into your vein.

**4) Stopping blood clots from forming in the tubes of your dialysis machine**

- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.
- Clexane Syringes are added to the tube leaving the body (arterial line) at the start of a dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a futher dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your bodyweight, if necessary.

**Giving yourself an injection of Clexane Syringes**

If you are able to give Clexane Syringes to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately. Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

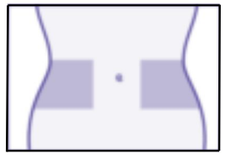
**Before injecting yourself with Clexane Syringes**

- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container
- Check the expiry date on the medicine. Do not use if the date has passed
- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe
- Make sure you know how much you are going to inject
- Check your stomach to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so talk to your doctor or nurse

**Instructions on injecting yourself with Clexane Syringes:**

**Preparing the injection site**

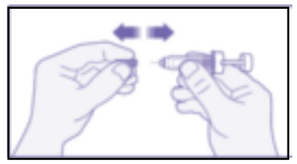
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
- Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
- Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

**Selecting your dose**

1) Carefully pull off the needle cap from the syringe. Throw away the cap.
- Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
- Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

**Injecting**

1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
   - Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.

3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out. You can now let go of the skin fold.

**When you have finished**

1) To avoid bruising, do not rub the injection site after you have injected yourself.

2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

**Changing anticoagulant medicine**

- **Changing from Clexane Syringes to blood thinners called vitamin-K antagonists (such as warfarin)**
  Your doctor will ask you to have blood tests called INR and tell you when to stop Clexane Syringes.

- **Changing from blood thinners called vitamin-K antagonists (such as warfarin) to Clexane Syringes**
  Stop taking the vitamin-K antagonist. Your doctor will ask you to have blood tests called INR and tell you when to start Clexane Syringes.

- **Changing from Clexane Syringes to treatment with direct oral anticoagulants**
  Stop taking Clexane Syringes. Start taking the direct oral anticoagulant 0 to 2 hours before the time you would have had the next injection, then continue as normal.

- **Changing from treatment with direct oral anticoagulants to Clexane Syringes**
  Stop taking the direct oral anticoagulant. Do not start treatment with Clexane Syringes until 12 hours after the final dose of the direct oral anticoagulant.

**If you use more Clexane Syringes than you should**

If you think that you have used too much or too little Clexane Syringes, tell your doctor or pharmacist or nurse immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Clexane Syringes, take them to a hospital casualty department straight away.

**If you forget to use Clexane Syringes**

If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

**If you stop using Clexane Syringes**

It is important for you to keep having Clexane Syringes injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

**Stop using Clexane Syringes and talk to a doctor or nurse straight away** if you get any signs of a severe allergic reaction (such as rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes).

**Stop using Clexane Syringes and seek medical attention immediately if you notice any of the following symptoms:**
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

Like other similar medicines to reduce blood clotting, Clexane Syringes may cause bleeding . This may be life-threatening. In some cases the bleeding may not be obvious.

**Talk to your doctor straight away if:**
- you have any bleeding that does not stop by itself
- you have signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling

Your doctor may decide to keep you under closer observation or change your medicine.

**You should tell your doctor straight away:**
- if you have any sign of blockage of a blood vessel by a blood clot such as:
- cramping pain, redness, warmth, or swelling in one of your legs
  – these are symptoms of deep vein thrombosis
- breathlessness, chest pain, fainting or coughing up blood
  – these are symptoms of a pulmonary embolism
- if you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may request you perform a blood test to check your platelet count.



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**Other side effects**

**Very common** (may affect more than 1 in 10 people):
- Bleeding
- Increases in liver enzymes

**Common** (may affect up to 1 in 10 people):
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts
- pink patches on your skin – these are more likely to appear in the area you have been injected with Lovenox Syringes
- skin rash (hives, urticaria)
- itchy red skin
- bruising or pain at the injection site
- decreased red blood cell count
- high platelet counts in the blood
- headache

**Uncommon** (may affect up to 1 in 100 people):
- sudden severe headache – this could be a sign of bleeding in the brain
- a feeling of tenderness and swelling in your stomach – you may have bleeding in your stomach
- large red irregularly shaped skin lesions with or without blisters
- skin irritation (local irritation)
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem

**Rare** (may affect up to 1 in 1,000 people):
- severe allergic reaction – the signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- increased potassium in your blood – this is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test
- an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- hair loss
- osteoporosis (a condition where your bones are more likely to break) after long term use
- tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic
- loss of control over your bladder or bowel (so you cannot control when you go to the toilet)
- hard mass or lump at the injection site.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5 How to store Lovenox Syringes

Do not use this medicine after the expiry date shown on the carton or syringe blister container. The expiry date refers to the last day of that month. If your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine, if your doctor tells you to. If your medicine becomes discoloured or shows any other signs of deterioration, consult your pharmacist who will tell you what to do.

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Do not store above 25°C.
- Do not refrigerate or freeze.
- Do not take the syringe out of the box until you need to use it.

Do not use this medicine if you notice a breach in the syringe, particulate matters in the solution, or an abnormal colour of the solution (see "What Lovenox Syringes look like and the contents of the pack").

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.



## 6 Contents of the pack and other information

**What Lovenox Syringes contains**
The active substance is enoxaparin sodium
Each mL contains 100mg enoxaparin sodium, equivalent to 10,000 IU of anti-Xa activity
Each pre-filled syringe of 0.2mL contains 2,000 IU (20mg) of enoxaparin sodium
Each pre-filled syringe of 0.4mL contains 4,000 IU (40mg) of enoxaparin sodium
Each pre-filled syringe of 0.6mL contains 6,000 IU (60mg) of enoxaparin sodium
Each pre-filled syringe of 0.8mL contains 8,000 IU (80mg) of enoxaparin sodium
Each pre-filled syringe of 1mL contains 10,000 IU (100mg) of enoxaparin sodium
The other ingredient is water for injections

**What Lovenox Syringes looks like and contents of the pack**
Lovenox Syringes are type 1 glass pre-filled syringes fitted with injection needles. Lovenox Syringes comes in packs of 6 or 10 syringes.

**Product Licence Holder and Manufacturer**
Lovenox Syringes are manufactured by Chinoin Pharmaceutical and Chemical Works Private Co.Ltd., Csanyikvolgy, 3510 Miskolc, Hungary and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE

POM PL 15184/0742 Lovenox 2,000IU (20mg)/0.2ml Syringes / Lovenox 4,000IU (40mg)/0.4ml Syringes / Lovenox 6,000IU (60mg)/0.6ml Syringes / Lovenox 8,000IU (800mg)/0.8ml Syringes / Lovenox 10,000IU (100mg)/1ml Syringes

Lovenox Syringes is a registered trademark of Sanofi Mature IP.

Revision date: 25/08/23

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: 01527 505414 to obtain the leaflet in a format suitable for you

Ref:0742/250823/11/F

# Lovenox® 2,000IU (20mg)/0.2ml Syringes / Lovenox® 4,000IU (40mg)/0.4ml Syringes / Lovenox® 6,000IU (60mg)/0.6ml Syringes / Lovenox® 8,000IU (80mg)/0.8ml Syringes / Lovenox® 10,000IU (100mg)/1ml Syringes

(enoxaparin sodium)

## Patient Information Leaflet

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Lovenox 2,000IU (20mg)/0.2ml Syringes /Lovenox 4,000IU (40mg)/0.4ml Syringes /Lovenox 6,000IU (60mg)/0.6ml Syringes / Lovenox 8,000IU (80mg)/0.8ml Syringes /Lovenox 10,000IU (100mg)/1ml Syringes and will be referred to as Lovenox Syringes throughout the rest of this leaflet.

**What is in this leaflet**


1 What Lovenox Syringes are and what they are used for
2 What you need to know before you use Lovenox Syringes
3 How to use Lovenox Syringes
4 Possible side effects
5 How to store Lovenox Syringes
6 Contents of the pack and other information


## 1 What Lovenox Syringes are and what they are used for

Lovenox Syringes contain the active substance called enoxaparin sodium. This belongs to a group of medicines called 'low molecular weight heparin' or LMWH.

**How Lovenox Syringes work**
Lovenox Syringes work in two ways:
1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stops them from causing you harm.
2) Stopping new blood clots from forming in your blood.

**What Lovenox Syringes are used for**
Lovenox Syringes can be used to:
- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
  - before and after an operation
  - when you have a short-term illness and will not be able to move around for some time.
  - if you have experienced a blood clot due to cancer to prevent further clots from forming
- Stop blood clots from forming when you have unstable angina (where not enough blood gets to your heart) or after a heart attack
- Stop blood clots from forming in the tubes of your dialysis machine (used for people with severe kidney problems).

## 2 What you need to know before you use Lovenox Syringes

**Do not use Lovenox Syringes if:**
- you are allergic to:
  - enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6)
  - heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin. Signs of an allergic reaction include: rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes.
- you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) within the last 100 days
- you have antibodies against enoxaparin in your blood
- you are bleeding heavily or have a condition with a high risk of bleeding, such as:
  - stomach ulcer, recent surgery of the brain or eyes, or recent bleeding stroke.
- you are using Lovenox Syringes to treat blood clots and are going to have within 24 hours:
  - a spinal or lumbar puncture
  - an operation with epidural or spinal anaesthesia.

Do not use Lovenox Syringes if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Lovenox Syringes.

**Warnings and precautions**
Lovenox Syringes should not be interchanged with other 'low molecular weight heparins' such as nadroparin, tinzaparin or dalteparin. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Lovenox Syringes if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have a history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high levels of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section 2, 'Other medicines and Lovenox Syringes')
- you have any problem with your spine or you have had spinal surgery. If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Lovenox Syringes.

For patients receiving doses higher than 210 mg/day, this medicine contains more than 24 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 1.2% of the recommended maximum daily intake of sodium for an adult.

**Tests and checks**
You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

**Use in children and adolescents**
The safety and efficacy of Lovenox Syringes has not been evaluated in children or adolescents.

**Other medicines and Lovenox Syringes**
Tell your doctor or pharmacist if you are taking or might take any other medicines.
- warfarin – used for thinning the blood
- aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots from forming (see section 3, 'Changing anticoagulant medicine')
- dextran injection – used as a blood replacer
- ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory medicines which are used to treat pain and swelling in arthritis and other conditions
- prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- medicines which increase potassium levels in your blood such as potassium salts, water pills, and some medicines for heart problems.

**Operations and anaesthetics**

If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Lovenox Syringes.

**Pregnancy and breast-feeding**

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

**Driving and using machines**

Lovenox Syringes do not affect the ability to drive and operate machinery.

It is advised that the trade name and batch number of the product you are using are recorded by your healthcare professional.

## 3 How to use Lovenox Syringes

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- Your doctor or nurse will normally give you Lovenox Syringes. This is because they need to be given as an injection.
- Lovenox Syringes are usually given by injection underneath the skin (subcutaneous).
- Lovenox Syringes can be given by injection into your vein (intravenous) after certain types of heart attack or operations.
- Lovenox Syringes can be added to the tube leaving the body (arterial line) at the start of a dialysis session.
- Do not inject Lovenox Syringes into a muscle.

**How much will be given to you**

- Your doctor will decide how much Lovenox Syringes to give you. The amount will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Lovenox Syringes.

**1) Treating blood clots that are in your blood**

- The usual dose is 150 IU (1.5 mg) for every kilogram of your bodyweight once a day or 100 IU (1 mg) for every kilogram of your bodyweight twice a day.
- Your doctor will decide how long you should receive Lovenox Syringes.

**2) Stopping blood clots from forming in your blood during operations or periods of limited mobility due to an illness**

- The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Lovenox Syringes each day.
- If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Lovenox Syringes each day.
- Your doctor will decide how long you should receive Lovenox Syringes.

**3) Stopping blood clots when you have unstable angina or after you have had a heart attack**

- Lovenox Syringes can be used for two different types of heart attack.
- The amount of Lovenox Syringes given to you will depend on your age and the kind of heart attack you have had.

NSTEMI (Non-ST segment Elevation Myocardial Infarction) type of heart attack:
- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Lovenox Syringes.



STEMI (ST segment Elevation Myocardial Infarction) type of heart attack if you are under 75 years old:
- An initial dose of 3,000 IU (30 mg) of Lovenox Syringes will be given as an injection into your vein.
- At the same time you will also be given Lovenox Syringes as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight, every 12 hours.
- Your doctor will normally ask you to take aspirin (acetylsalicylic acid) as well.
- Your doctor will decide how long you should receive Lovenox Syringes.

STEMI type of heart attack if you are 75 years old or older:
- The usual dose is 75 IU (0.75 mg) for every kilogram of your bodyweight, every 12 hours.
- The maximum amount of Lovenox Syringes given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Lovenox Syringes.

For patients that have an operation called percutaneous coronary intervention (PCI):
- Depending on when you were last given Lovenox Syringes, your doctor may decide to give an additional dose of Lovenox Syringes before a PCI operation.
  This is by injection into your vein.

**4) Stopping blood clots from forming in the tubes of your dialysis machine**

- The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.
- Lovenox Syringes are added to the tube leaving the body (arterial line) at the start of a dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a futher dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your bodyweight, if necessary.

**Giving yourself an injection of Lovenox Syringes**

If you are able to give Lovenox Syringes to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained how to do so. If you are not sure what to do, talk to your doctor or nurse immediately. Performing the injection properly under the skin (called “subcutaneous injection”) will help reduce pain and bruising at the injection site.

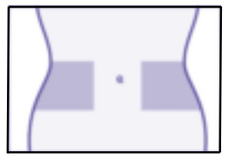
**Before injecting yourself with Lovenox Syringes**

- Collect together the items that you need: syringe, alcohol swab or soap and water, and sharps container
- Check the expiry date on the medicine. Do not use if the date has passed
- Check the syringe is not damaged and the medicine in it is a clear solution. If not, use another syringe
- Make sure you know how much you are going to inject
- Check your stomach to see if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so talk to your doctor or nurse

**Instructions on injecting yourself with Lovenox Syringes:**

**Preparing the injection site**

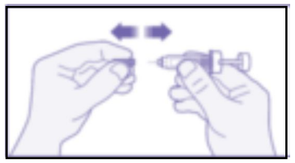
1) Choose an area on the right or left side of your stomach. This should be at least 5 centimetres away from your belly button and out towards your sides.
- Do not inject yourself within 5cm of your belly button or around existing scars or bruises.
- Change the place where you inject between the left and right sides of your stomach, depending on the area you last injected.



2) Wash your hands. Cleanse (do not rub) the area that you will inject with an alcohol swab or soap and water.
3) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

**Selecting your dose**

1) Carefully pull off the needle cap from the syringe. Throw away the cap.
- Do not press on the plunger before injecting yourself to get rid of air bubbles. This can lead to a loss of the medicine.
- Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).



2) When the amount of medication in the syringe already matches your prescribed dose, there is no need to adjust the dose. You are now ready to inject.
3) When the dose depends on your body weight, you may need to adjust the dose in the syringe to match the prescribed dose. In that case, you can get rid of any extra medicine by holding the syringe pointing down (to keep the air bubble in the syringe) and ejecting the extra amount into a container.
4) A drop may appear at the tip of the needle. If this occurs, remove the drop before injecting by tapping on the syringe with the needle pointing down. You are now ready to inject.

**Injecting**

1) Hold the syringe in the hand you write with (like a pencil). With your other hand, gently pinch the cleaned area of your stomach between your forefinger and thumb to make a fold in the skin.
   - Make sure you hold the skin fold throughout the injection.
2) Hold the syringe so that the needle is pointing straight down (vertically at a 90° angle). Insert the full length of the needle into the skin fold.

3) Press down on the plunger with your thumb. This will send the medication into the fatty tissue of the stomach. Complete the injection using all of the medicine in the syringe.
4) Remove the needle from the injection site by pulling it straight out. You can now let go of the skin fold.

**When you have finished**

1) To avoid bruising, do not rub the injection site after you have injected yourself.

2) Drop the used syringe into a sharps container. Close the container lid tightly and place the container out of reach of children. When the container is full, dispose of it as your doctor or pharmacist has instructed.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

**Changing anticoagulant medicine**

- **Changing from Lovenox Syringes to blood thinners called vitamin-K antagonists (such as warfarin)**
  Your doctor will ask you to have blood tests called INR and tell you when to stop Lovenox Syringes.

- **Changing from blood thinners called vitamin-K antagonists (such as warfarin) to Lovenox Syringes**
  Stop taking the vitamin-K antagonist. Your doctor will ask you to have blood tests called INR and tell you when to start Lovenox Syringes.

- **Changing from Lovenox Syringes to treatment with direct oral anticoagulants**
  Stop taking Lovenox Syringes. Start taking the direct oral anticoagulant 0 to 2 hours before the time you would have had the next injection, then continue as normal.

- **Changing from treatment with direct oral anticoagulants to Lovenox Syringes**
  Stop taking the direct oral anticoagulant. Do not start treatment with Lovenox Syringes until 12 hours after the final dose of the direct oral anticoagulant.

**If you use more Lovenox Syringes than you should**

If you think that you have used too much or too little Lovenox Syringes, tell your doctor or pharmacist or nurse immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Lovenox Syringes, take them to a hospital casualty department straight away.

**If you forget to use Lovenox Syringes**

If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

**If you stop using Lovenox Syringes**

It is important for you to keep having Lovenox Syringes injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## 4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**

**Stop using Lovenox Syringes and talk to a doctor or nurse straight away** if you get any signs of a severe allergic reaction (such as rash, difficulty breathing or swallowing, swelling of the face, lips, tongue, oral cavity, throat or eyes).

**Stop using Lovenox Syringes and seek medical attention immediately if you notice any of the following symptoms:**
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalized exanthematous pustulosis).

Like other similar medicines to reduce blood clotting, Lovenox Syringes may cause bleeding . This may be life-threatening. In some cases the bleeding may not be obvious.

**Talk to your doctor straight away if:**
- you have any bleeding that does not stop by itself
- you have signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling.

Your doctor may decide to keep you under closer observation or change your medicine.

**You should tell your doctor straight away:**
- if you have any sign of blockage of a blood vessel by a blood clot such as:
  - cramping pain, redness, warmth, or swelling in one of your legs – these are symptoms of deep vein thrombosis
  - breathlessness, chest pain, fainting or coughing up blood – these are symptoms of a pulmonary embolism
- if you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may request you perform a blood test to check your platelet count.



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