

PACKAGE LEAFLET: INFORMATION FOR THE USER
Clexane® Syringes 10,000 IU (100 mg)/1 ml solution for injection in pre-filled syringes
(enoxaparin sodium)

Your medicine is called **Clexane 100mg/1ml Syringes** but will be referred to as **Clexane** throughout the remainder of this leaflet. This product is also available in multiple strengths and other strengths will be referred to throughout the 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.

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 it needs 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 further 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.