

Package leaflet: Information for the user

Ghemaxan 8,000 IU (80 mg)/0.8 mL solution for injection in pre-filled syringe

Enoxaparin sodium

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ghemaxan is and what it is used for
2. What you need to know before you use Ghemaxan
3. How to use Ghemaxan
4. Possible side effects
5. How to store Ghemaxan
6. Contents of the pack and other information

1. What Ghemaxan is and what it is used for

Ghemaxan contains the active substance called enoxaparin sodium, which is a low molecular weight heparin (LMWH).

Ghemaxan works in two ways.

- 1) It stops existing blood clots from getting any bigger. This helps your body to break them down and stop them causing you harm.
- 2) It stops blood clots forming in your blood.

Ghemaxan can be used to:

- treat blood clots in your blood
- stop blood clots forming in your blood in the following situations:
 - Before and after an operation
 - When you have an acute illness and face period of limited mobility
 - If you have experienced a blood clot due to cancer to prevent further clots from forming
 - When you have unstable angina (a condition when not enough blood gets to your heart)
 - After a heart attack
- stop blood clots forming in the tubes of your dialysis machine (used for people with severe kidney problems)

2. What you need to know before you use Ghemaxan

Do not use Ghemaxan

- if you are allergic to enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you are allergic to heparin or other Low Molecular Weight Heparins such as nadroparin, tinzaparin or dalteparin
- if you have had a reaction to heparin within the last 100 days that caused a severe drop in the number of your clotting cells (platelets) - this reaction is called heparin-induced thrombocytopenia - or if you have antibodies against enoxaparin in your blood
- if 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), including recent haemorrhagic (bleeding) stroke.
- if you are using Ghemaxan to treat blood clots in your body and you are going to receive spinal or epidural anaesthesia or lumbar puncture within 24 hours.

Warnings and precautions

Ghemaxan should not be used interchangeably with other medicines belonging to the group of low molecular weight heparins. 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 Ghemaxan if:

- you have ever had a reaction to heparin that caused a severe drop in the number of your platelets
- you are going to receive spinal or epidural anaesthesia or lumbar puncture (see Operations and Anaesthetics): a delay should be respected between Ghemaxan use and this procedure
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have 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 level of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section below “Other medicines and Ghemaxan”)

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.

Other medicines and Ghemaxan

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use 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 also in section 3 “Changing anticoagulant treatment”)
- Dextran injection - used as a blood replacer
- Ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory agents, 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, some medicines for heart problems.

Operations and anaesthetics

If you are going to have a spinal puncture or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Ghemaxan. See “Do not use Ghemaxan”. Also tell your doctor if you have any problem with your spine or if you have ever had spinal surgery.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, 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.

Driving and using machines

Ghemaxan does not affect the ability to drive and use machines.

Ghemaxan contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium-free’.

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 Ghemaxan

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 Ghemaxan. This is because it needs to be given as an injection.
- When you go home, you may need to continue to use Ghemaxan and give it to yourself (see instructions below on how to do this).
- Ghemaxan is usually given by injection beneath the skin (subcutaneous).
- Ghemaxan can be given by injection into your vein (intravenous) after certain types of heart attack or operation.
- Ghemaxan can be added to the tube leaving the body (arterial line) at the start of the dialysis session.

Do not inject Ghemaxan into a muscle.

How much will be given to you

- Your doctor will decide how much Ghemaxan 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 Ghemaxan.

1) Treating blood clots in your blood

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

2) Stopping blood clots forming in your blood in the following situations:

a) Operation 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 Ghemaxan each day.
- If you are going to have an operation, your first injection will usually be 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 Ghemaxan each day.
- Your doctor will decide how long you should receive Ghemaxan.

b) After you have had a heart attack

Ghemaxan can be used for two different types of heart attack called STEMI (ST-segment elevation myocardial infarction) or non STEMI (NSTEMI). The amount of Ghemaxan given to you will depend on your age and the kind of heart attack you have had.

NSTEMI type of heart attack:

- The usual amount is 100 IU (1 mg) for every kilogram of weight, 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 Ghemaxan.

STEMI type of heart attack if you are under 75 years old:

- An initial dose of 3,000 IU (30 mg) of Ghemaxan will be given as an injection into your vein.
- At the same time, you will also be given Ghemaxan as an injection beneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your weight, 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 Ghemaxan.

STEMI type of heart attack if you are aged 75 years or older:

- The usual dose is 75 IU (0.75 mg) for every kilogram of your weight, every 12 hours.
- The maximum amount of Ghemaxan given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Ghemaxan.

For patients having an operation called Percutaneous Coronary Intervention (PCI):

Depending on when you were last given Ghemaxan, your doctor may decide to give an additional dose of Ghemaxan before a PCI operation. This is by injection into your vein.

3) 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 weight
- Ghemaxan is added to the tube leaving the body (arterial line) at the start of the 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 weight, if necessary.

Method of administration

The pre-filled syringe is ready for immediate use.

This medicine must not be administered by the intramuscular route.

Injection through the arterial line of the extracorporeal circuit

In order to prevent blood clots forming in the tubes of your dialysis machine, this medicine will be given by an injection into the tube leaving the body (arterial line).

Intravenous injection technique (for acute STEMI indication only)

In the treatment of acute STEMI, treatment should begin with a single rapid injection into your vein (intravenous injection), immediately followed by an injection beneath the skin (subcutaneous injection).

Subcutaneous injection (injection beneath the skin) technique

This medicine is usually given by injection underneath the skin (subcutaneous).

Injection is best done when the patient is lying down by deep subcutaneous injection. Administration should be alternated between the left and right anterolateral or posterolateral abdominal wall. The whole length of the needle should be introduced vertically into a skin fold held between the thumb and index finger. The skin fold should not be released until the injection is complete.

Do not rub the injection site after administration.

If you use the pre-filled 20 mg and 40 mg syringe, do not remove the air bubble from the syringe prior to injection, as this may result in a reduction of the dose.

The pre-filled syringe is intended for single use only.

Do not use this medicine if you notice any visible change in the appearance of the solution.

How to give yourself an injection of Ghemaxan

If you are able to give Ghemaxan 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.

Before injecting yourself with Ghemaxan

- 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.
- Do not use this medicine if you notice any change in the appearance of the product.
- Make sure you know how much you are going to inject.
- Check your abdomen 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.
- Decide where you are going to inject the medicine. Change the place where you inject each time from the right to the left side of your stomach. Ghemaxan should be injected just under the skin on your stomach, but not too near the belly button or any scar tissue (at least 5 cm away from these).

The pre-filled syringe is intended for single, one-time use only and is available in the following presentations:

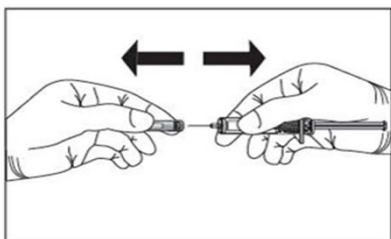
- with a needle guard.
- without a needle guard.

Instructions on injecting yourself with Ghemaxan:

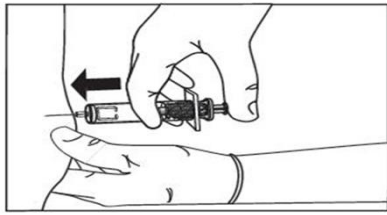
You should be lying down and Ghemaxan administered by deep SC injection. Choose an area on the right or left side of your stomach. This should be at least 5 cm away from your belly button and out towards your sides. Ghemaxan pre-filled syringes and graduated pre-filled syringes are for single, one-time use only and are available with and without a needle guard.

Remove the pre-filled syringe from the blister packaging by peeling at the arrow as directed on the blister. Do not remove by pulling on the plunger, as this may damage the syringe.

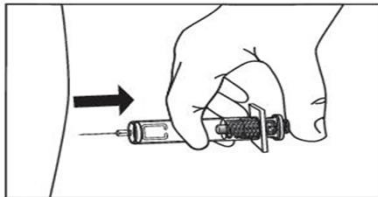
- 1) Remove the needle guard by pulling it straight off the syringe.



- 2) Gently pinch the cleaned area of your abdomen between your forefinger and thumb to make a fold in the skin. Make sure you hold the skin fold throughout the injection. Insert the full length of the needle into the skin fold and inject the medicine by pushing the plunger to the bottom of the syringe.



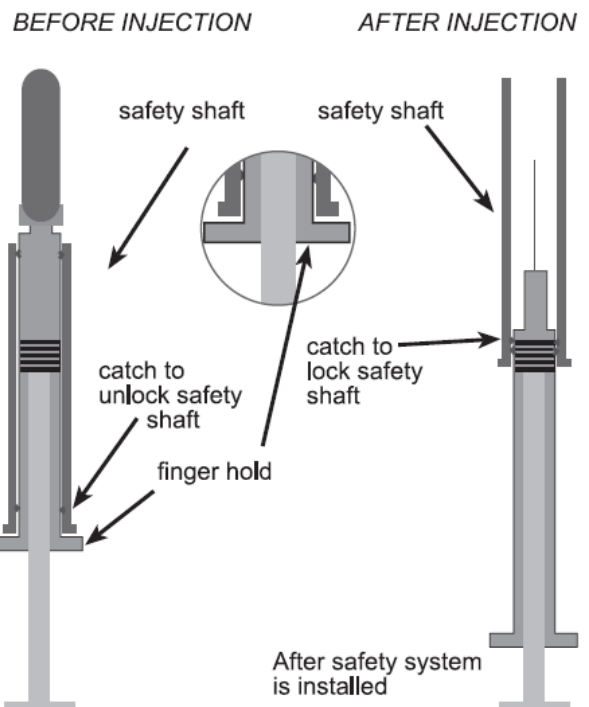
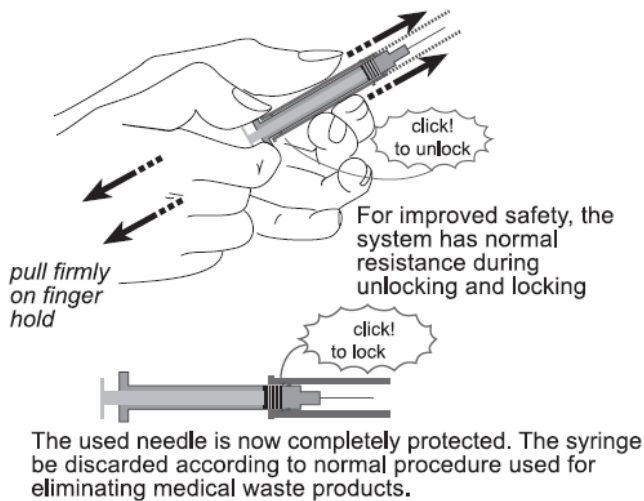
3) Remove the syringe from the injection site keeping your finger on the plunger rod. You may now release the skin fold. To minimise bruising, do not rub the injection site after completion of the injection.



4a) For the pre-filled syringes equipped with a needle guard

After completion of the injection firmly hold the syringe tube with one hand. With the other hand hold the base, "wings", of the syringe, and pull it until you hear a clicking sound. Now the used needle is completely protected.

The safety shaft is provided with a catch to unlock and lock the system.



Immediately dispose of the syringe in the appropriate container.

4b) For the pre-filled syringes not equipped with a needle guard
Immediately dispose of the syringe in the appropriate container.



Changing anticoagulant treatment

- *Changing from Ghemaxan to blood thinners called vitamin-K antagonists (e.g. warfarin)*
Your doctor will request you perform blood tests called INR and tell you when to stop Ghemaxan accordingly.
- *Changing from blood thinners called vitamin K antagonists (e.g. warfarin) to Ghemaxan*
Stop taking the vitamin K antagonist. Your doctor will request you perform blood tests called INR and tell you when to start Ghemaxan accordingly.
- *Changing from Ghemaxan to treatment with direct oral anticoagulants*
Stop taking Ghemaxan. Start taking the direct oral anticoagulant 0-2 hours before the time you would have had the next injection, then continue as normal.
- *Changing from treatment with direct oral anticoagulants to Ghemaxan*
Stop taking the direct oral anticoagulant. Do not start treatment with Ghemaxan (and associated names) until 12 hours after the final dose of the direct oral anticoagulant.

Use in children and adolescents

The safety and efficacy of Ghemaxan (and associated names) have not been evaluated in children or adolescents.

If you use more Ghemaxan than you should

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

If you forget to use Ghemaxan

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 Ghemaxan

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse. It is important for you to keep having Ghemaxan injections until your doctor decides to stop them. If you stop, you could get a blood clot, which can be very dangerous.

4. Possible side effects

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

Serious side effects

Stop using Ghemaxan and talk to a doctor or nurse at once if you get any signs of a severe allergic reaction (such as difficulty breathing, swelling of the lips, mouth, throat or eyes).

Stop using Ghemaxan 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 generalised exanthematous pustulosis).

Like other similar medicines, to reduce blood clotting, Ghemaxan may cause bleeding, which may potentially be life-threatening. In some cases, the bleeding may not be obvious.

Talk to your doctor straight away if:

- you have any bleeding event 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.

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 Ghemaxan.
- 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).
- You notice 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, 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 Website: 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 Ghemaxan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible change in the appearance of the solution.

Do not freeze.

Ghemaxan pre-filled syringes are for single dose use only. Discard any unused medicine.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ghemaxan contains

- Each pre-filled syringe contains enoxaparin sodium 8,000 IU anti-Xa activity (equivalent to 80 mg) in 0.8 mL water for injections
- The other ingredient is water for injections

What Ghemaxan looks like and contents of the pack

Ghemaxan is a clear, colourless to pale yellow solution for injection in a Type I glass pre-filled syringe fitted with an injection needle and needle shield. The syringe may or may not be fitted with a needle guard.

1. Syringe equipped with a needle guard

Packs of 2, 6 or 10 pre-filled syringes and multipacks containing 12 (2 packs of 6), 20 (2 packs of 10), 24 (4 packs of 6), 30 (3 packs of 10), 50 (5 packs of 10) and 90 (9 packs of 10) pre-filled syringes

2. Syringe not equipped with a needle guard

Packs of 2 and 10 graduated pre-filled syringes and multipack containing 30 (3 packs of 10) graduated pre-filled syringes

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Chemi S.p.A.

Via dei Laboratori 54 - 20092 Cinisello Balsamo (MI)

Tel: +39.02.64431

Fax: +39.02. 6128960
e-mail: chemi@chemi.com

Manufacturer

Italfarmaco S.p.A.
Viale F. Testi, 330
20126 Milano

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Ghemaxan
Germany: Hepaxane
Denmark: Ghemaxan
Greece: Havetra
Spain: Hepaxane
Finland: Ghemaxan
Italy: Ghemaxan
The Netherlands: Ghemaxan
Norway: Ghemaxan
Ireland: Ghemaxan
Austria: Ghemaxan
France: Ghemaxan
Sweden: Ghemaxan
Portugal: Hepaxane
Hungary: Hepaxane
Romania: Hepaxane
Slovakia: Ghemaxan

This leaflet was last revised in January 2023

Detailed information on this medicine is available on the web site of MHRA