Package leaflet: Information for the user

Enoxaparin sodium Ledraxen 2,000 IU (20 mg)/0.2 mL solution for injection in pre-filled syringe
Enoxaparin sodium Ledraxen 4,000 IU (40 mg)/0.4 mL solution for injection in pre-filled syringe
Enoxaparin sodium Ledraxen 6,000 IU (60 mg)/0.6 mL solution for injection in pre-filled syringe
Enoxaparin sodium Ledraxen 8,000 IU (80 mg)/0.8 mL solution for injection in pre-filled syringe
Enoxaparin sodium Ledraxen 10,000 IU (100 mg)/1 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 containsimportant 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, pharmacist or nurse. This includes any possible sideeffects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Enoxaparin sodium Ledraxen is and what it is used for

Enoxaparin sodium Ledraxen contains the active substance called enoxaparin sodium that is alow molecular weight heparin (LMWH).

Enoxaparin sodium Ledraxen works in two ways.
1) Stopping existing blood clots from getting any bigger. This helps your body to break themdown and stops them from causing you harm
2) Stopping new blood clots from forming in your blood.

Enoxaparin sodium Ledraxen 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 Enoxaparin sodium Ledraxen

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

Warnings and precautions
Enoxaparin sodium Ledraxen 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 Enoxaparin sodium Ledraxen if:

- you have ever had a reaction to heparin that caused a severe drop in the number of yourplatelets
- 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 (calleddiabetic 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.
- 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 Enoxaparin sodium Ledraxen.

This medicine contains less than 1 mmol (23 mg) of sodium per dose, i.e. it is essentially "sodium-free".

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.

Other medicines and Enoxaparin sodium Ledraxen
Tell your doctor or pharmacist if you are taking 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 stopblood clots from forming (see also in section 3, "Changing of anticoagulant medicine")
- Dextran injection – used as a blood replacer
- Ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatoryagents which are used to treat pain and swelling in arthritis and other conditions
- Prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis andother conditions
- Medicines which increase potassium level 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 you doctor that you are using Enoxaparin sodium Ledraxen.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor orpharmacist for advice before taking this medicine.
If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developingblood 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 takingthis medicine.

Children and adolescents
The safety and efficacy of Enoxaparin sodium Ledraxen has not been evaluated in children or adolescents.

Driving and using machines
Enoxaparin sodium Ledraxen does 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 yourhealthcare professional.

3. How to use Enoxaparin sodium Ledraxen

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

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

How much will be given to you
- Your doctor will decide how much Enoxaparin sodium Ledraxen to give you. The a 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 Enoxaparin sodium Ledraxen .

1. Treating blood clots that are 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 Enoxaparin sodium Ledraxen .

2. Stopping blood clots forming in your blood during 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 Enoxaparin sodium Ledraxen each day.
- If you are going to have an operation your first injection will be usually given 2 hours or12 hours before your operation.
- If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg)of Enoxaparin sodium Ledraxen each day.
- Your doctor will decide how long you should receive Enoxaparin sodium Ledraxen.

3. Stopping blood clots when you have unstable angina or after you have had a heart attack
- Enoxaparin sodium Ledraxen.can be used for two different types of heart attack.
- The amount of Enoxaparin sodium Ledraxen 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 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 Enoxaparin sodium Ledraxen .

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 Enoxaparin sodium Ledraxen will be given as injection into your vein.
- At the same time you will also be given Enoxaparin sodium Ledraxen as an injection underneath 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 Enoxaparin sodium Ledraxen .

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 weight, every 12 hours.
- The maximum amount of Enoxaparin sodium Ledraxen given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Enoxaparin sodium Ledraxen .

For patients that have an operation called percutaneous coronary intervention (PCI):

Depending on when you were last given Enoxaparin sodium Ledraxen , your doctor may decide to give an additional dose of Enoxaparin sodium Ledraxen 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 weight.
- Enoxaparin sodium Ledraxen 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, yourdoctor may give you a futher dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your weight, if necessary.

Giving yourself an injection of Enoxaparin sodium Ledraxen

If you are able to give Enoxaparin sodium Ledraxen 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 Enoxaparin sodium Ledraxen

• 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 FOR USE: PREFILLED SYRINGE

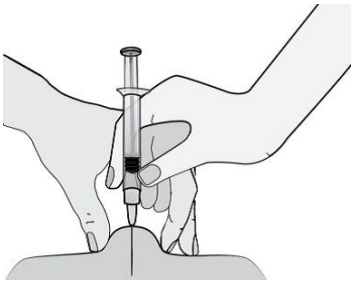
Appropriate use of syringes is necessary to reduce the risk of pain and appearance of bruises at the injection site. Be careful to follow the instructions.

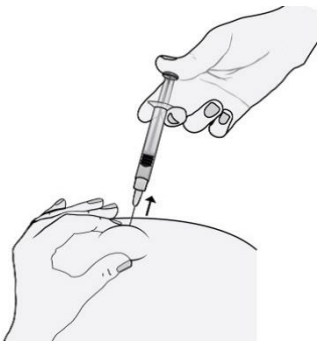
Instructions for syringes without safety system

• Preparation of the injection site:
Before performing the injection, wash your hands and dry them. Use a cotton ball to clean (without rubbing) the area chosen for the injection.
Choose a different area of the stomach for each injection.

• Remove the protective cap from the needle.
The appearance of a drop at the end of the needle is possible. In this case, remove the drop before injection by tapping on the body of the syringe (with the needle pointing downwards).

• Perform the injection:
The pre-filled syringe is ready for immediate use. Choose an area on the right or left side of your stomach. This should be at least 5 cm away from your belly button (navel) and out towards your sides. Hold the syringe so that the needle is pointing downwards (vertically at a 90 ° angle), into the thickness of a skin fold pinched between the thumb and index finger of the operator. The fold should be held throughout the entire injection.



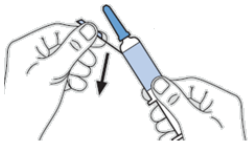


• Immediately throw away the syringe in the appropriate container.
Any unused medicinal product or waste material should be disposed of in accordance with localrequirements.

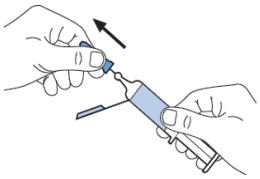
Instructions for syringes with safety system

• Preparation of the injection site:
Before performing the injection, wash your hands and dry them. Use a cotton ball to clean (without rubbing) the area chosen for the injection.
Choose a different area of the stomach for each injection.

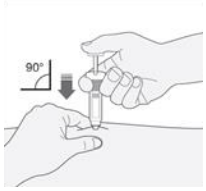
• First, bend the trap toward the side by approximately 90 degrees. Important: do not remove the cap before bending the trap.



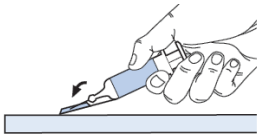
• Remove the protective cap from the needle.
The appearance of a drop at the end of the needle is possible. In this case, remove the drop before injection by tapping on the body of the syringe (with the needle pointing downwards).



• Perform the injection:
The pre-filled syringe is ready for immediate use. Choose an area on the right or left side of your stomach. This should be at least 5 cm away from your belly button (navel) and out towards your sides. Hold the syringe so that the needle is pointing downwards (vertically at a 90 º angle), into the thickness of a skin fold pinched between the thumb and index finger of the operator. The fold should be held throughout the entire injection.



• Secure the needle-trap:
Place the trap against a hard, stable surface, using one hand. Important: Do not use your finger to secure the needle in the trap. Then press down the trap. Bend the trap until the needle audibly clicks into the plastic part.



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 medicinal product or waste material should be disposed of in accordance with local requirements.

Changing of anticoagulant treatment

- *Changing from Enoxaparin sodium Ledraxen 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 Enoxaparin sodium Ledraxen.

- *Changing from blood thinners called vitamin-K antagonists (e.g. warfarin) to Enoxaparin sodium Ledraxen* Stop taking the vitamin-K antagonist. Your doctor will request you perform blood tests called INRand tell you when to start Enoxaparin sodium Ledraxen.

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

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

If you forget to use Enoxaparin sodium Ledraxen
If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a doubledose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you donot miss a dose.

If you stop using Enoxaparin sodium Ledraxen
It is important for you to keep having Enoxaparin sodium Ledraxen 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 or 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 Enoxaparin sodium Ledraxen 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 enoxaparin 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, Enoxaparin sodium Ledraxen 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.

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 plateletcounts.
- Pink patches on your skin. These are more likely to appear in the area you have been injectedwith Enoxaparin sodium Ledraxen .
- 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 couldbe 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) whenyou have had a spinal puncture or a spinal anaesthetic.
- Lost 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 national reporting system HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on **t**he safety of this medicine.

5. How to store Enoxaparin sodium Ledraxen

Do not store above 25°C.
Do not freeze.

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 label. The expiry date refers to thelast day of that month.

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 Enoxaparin Ledraxen looks like and contents of the pack")..

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

6. Contents of the pack and other information

What Enoxaparin sodium Ledraxen contains

2,000 IU (20 mg)/0.2 mL solution for injection
- The active substance is enoxaparin sodium
- Each mL contains 100 mg of enoxaparin sodium

Each pre-filled syringe of 0.2 mL contains 2,000 IU anti-Xa activity (equivalent to 20 mg) of enoxaparin sodium
- The other ingredient is water for injections.

4,000 IU (40 mg)/0.4 mL solution for injection
- The active substance is enoxaparin sodium
- Each mL contains 100 mg of enoxaparin sodium

Each pre-filled syringe of 0.4 mL contains 4,000 IU anti-Xa activity (equivalent to 40 mg) of enoxaparin sodium
- The other ingredient is water for injections.

6,000 IU (60 mg)/0.6 mL solution for injection
- The active substance is enoxaparin sodium
- Each mL contains 100 mg of enoxaparin sodium

Each pre-filled syringe of 0.6 mL contains 6,000 IU anti-Xa activity (equivalent to 60 mg) of enoxaparin sodium
- The other ingredient is water for injections.

8,000 IU (80 mg)/0.8 mL solution for injection
- The active substance is enoxaparin sodium
- Each mL contains 100 mg of enoxaparin sodium

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

10,000 IU (100 mg)/1 mL solution for injection
- The active substance is enoxaparin sodium
- Each mL contains 100 mg of enoxaparin sodium

Each pre-filled syringe of 1.0 mL contains 10,000 IU anti-Xa activity (equivalent to 100 mg) of enoxaparin sodium
- The other ingredient is water for injections.

What Enoxaparin sodium Ledraxen looks like and contents of the pack

2,000 IU (20 mg)/0.2 mL solution for injection
Colourless or light yellow transparent liquid
0.2 mL of solution in a clear, colourless, type I neutral glass syringe barrel with fixed needle and needle cap closed by chlorobutyl rubber stopper and a purple propylene plunger rod (with or without safety system).
Packs of 1, 2, 6, 10, 20 or 50 pre-filled syringes.

4,000 IU (40 mg)/0.4 mL solution for injection
Colourless or light yellow transparent liquid
0.4 mL of solution in a clear, colourless, type I neutral glass syringe barrel with fixed needle and needle cap closed by chlorobutyl rubber stopper and a yellow propylene plunger rod (with or without safety system).
Packs of 1, 2, 6, 10, 20, 30 or 50 pre-filled syringes.

6,000 IU (60 mg)/0.6 mL solution for injection
Colourless or light yellow transparent liquid
0.6 mL of solution in a clear, colourless, type I neutral glass graduated syringe barrel with fixed needle and needle cap closed by chlorobutyl rubber stopper and an orange propylene plunger rod (with or without safety system).
Packs of 1, 2, 6, 10, 12, 20, 24, 30 or 50 pre-filled syringes.

8,000 IU (80 mg)/0.8 mL solution for injection
Colourless or light yellow transparent liquid
0.8 mL of solution in a clear, colourless, type I neutral glass graduated syringe barrel with fixed needle and needle cap closed by chlorobutyl rubber stopper and a brown propylene plunger rod

(with or without safety system).
Packs of 1, 2, 6, 10, 12, 20, 24, 30 or 50 pre-filled syringes.

10,000 IU (100 mg)/1 mL solution for injection
Colourless or light yellow transparent liquid
1 mL of solution in a clear, colourless, type I neutral glass graduated syringe barrel with fixed needle and needle cap closed by chlorobutyl rubber stopper and a grey propylene plunger rod (with or without safety system).
Packs of 1, 2, 6, 10, 12, 20, 24 or 30 pre-filled syringes.

For 0.2 mL and 0.4mL syringes, the syringes are not graduated.
For 0.6 mL, 0.8 mL and 1 mL syringes, the syringes are graduated.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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ZAC des Suzots
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F-63450 Saint-Amant Tallende
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This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom	Ledraxen
Sweden:	Enoxaparin Ledraxen
Spain:	Enoxaparina Ledraxen
France:	Enoxaparine Arrow
Latvia:	Enoxaparin sodium Ledraxen
Lettonia	Enoxaparin sodium Ledraxen
Austria:	Enoxaparin Ledraxen
Cyprus:	Ledraxen
Czech Republic:	Enoxaparin sodium Ledraxen
Estonia:	Enoxaparin sodium Ledraxen
Finland:	Enoxaparin Ledraxen
Croatia:	Enoksaparinnatrij Ledraxen
Germany:	Enoxaparin Ledraxen
Norway	Enoxaparin Ledraxen
Poland:	Enoxaparin sodium Ledraxen
Portugal:	Enoxaparin Ledraxen
Slovakia:	Ledraxen
Slovenia:	Enoksaparin Ledraxen

This leaflet was last revised in February 2023.

Other sources of information

Detailed information on this medicine is available on the website of Health Products Regulatory Authority (HPRA).