

CLEXANE®

Enoxaparin Sodium 2,000/0.2ml- 4,000/0.4ml - 6,000/0.6ml

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What Clexane is used for

The name of your medicine is Clexane. Clexane contains a medicine called enoxaparin sodium. This belongs to a group of medicines called Low Molecular Weight Heparins.

Clexane is used to prevent:

- Formation of blood clots in the veins (thromboembolic disorders), including in orthopedic and general surgery.
- Formation of blood clots in the veins of bedridden patients admitted because of a sudden illness, including heart failure, acute respiratory failure, severe infections or rheumatic diseases.
- Blood clotting (coagulation) in the extracorporeal circulation by hemodialysis (kidney replacement therapy).

Clexane is used to treat:

- Blood clots in the veins (deep vein thrombosis) with or without pulmonary embolism (a blockage of an artery by a blood clot).
- A sudden painful feeling tightness in the chest (unstable angina) and some form of a heart attack (myocardial infarction without Q-wave), in combination with acetylsalicylic acid (aspirin).
- An acute heart attack (STEMI: ST-segment Elevation Myocardial Infarction) in patient not for subsequent coronary angioplasty- Percutaneous Coronary Intervention (PCI).

How Clexane works

Clexane works in two ways.

- (i) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stop them causing you harm
- (ii) Stopping blood clots forming in your blood

Before you use Clexane

When you must not use it

Do not use Clexane if:

- You are allergic (hypersensitive) to:
 - (i) enoxaparin sodium or any of the other ingredients of Clexane ;
 - (ii) heparin or other Low Molecular Weight Heparins

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

- You have a problem with bruising or bleeding too easily
- You have an ulcer in your stomach or gut (intestine)
- You have had a stroke caused by bleeding in the brain
- You have kidney problems (see "People with kidney problems")
- You have an infection in your heart
- You are using heparin to treat blood clots (see "Taking other medicines")

Before you start to use it

Check with your doctor or pharmacist or nurse before having this medicine if:

- If you have severe abnormalities in blood clotting.
- If this medicine with an anesthetic (anesthesia) was used, consult your doctor immediately if you experience the following symptoms occur: pain in the middle of the back, motor disorders (movements) and sensory disturbances (numbness or weakness of the lower limbs), functional disorders of the bladder or of the intestine.
- If you are elderly, given the increased risk of bleeding.
- If you suffer from reduced kidney function or liver (renal or hepatic).
- If you are underweight or overweight

(<40kg and > 100kg).

- If you have severe, uncontrolled high blood pressure.
- If you have a stomach or intestinal ulcer or have had.
- If you have recently had a heart attack.
- If you have certain disorders of the retina caused by diabetes or bleeding (hemorrhagic or diabetic retinopathy).
- If you have mechanical heart valves, especially if you are pregnant. Always consult your doctor.
- If you need to undergo surgical interventions at the level of the nerves, eyes, or the coronary artery.
- In some cases where there is a shortage of platelets. Your doctor will regularly check your blood platelets.
- If you have a history of spinal (with respect to the spine) surgery or has spinal deformity.
- If you are taking other medication, carefully read the section "Taking other medicines".

Taking other medicines

Please tell your doctor, pharmacist or nurse if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Clexane can affect the way some other medicines work. Also some medicines can affect the way Clexane works.

Stop using these medicines unless your doctor tells you otherwise:

- Heparin - used to treat blood clots

Tell your doctor if you are taking any of the following medicines:

- Warfarin – used for thinning the blood
- Aspirin, dipyridamole, clopidogrel or other medicines - used to stop blood clots forming
- Dextran injection - used to replace blood volume
- Ibuprofen, diclofenac, ketorolac or other medicines - used to treat pain and swelling in arthritis and other illnesses

- Water tablets (diuretics) such as spironolactone, triamterene or amiloride. These may increase the levels of potassium in your blood when taken with Clexane.

Your doctor may change one of your medicines or take regular blood tests to check that taking these medicines with Clexane is not causing you any harm.

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 having Clexane. Tell also your doctor if you have any problem with your spine or if you have ever had spinal surgery.

Pregnancy and breast-feeding

Talk to your doctor before you are given this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

You should not use this medicine if you **are pregnant and have a mechanical heart valve** as you may be at increased risk of developing blood clots. Your doctor should discuss this with you.

You should not breast-feed whilst using Clexane. If you are planning to breast-feed, talk to your doctor, pharmacist or nurse.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

How to use Clexane

Use Clexane exactly as your doctor has told you. If you are unsure about the correct use, please contact your doctor or pharmacist.

Method and route of administration:

Clexane is given subcutaneously (under the skin), intravenously (into a vein) or administered through the arterial line of the dialysis unit. The route of administration depends on the indication for which you are being treated as mentioned under "The usual dose is:"

Clexane should not be given intramuscularly (into the muscle). The pre-filled syringes are ready to use and must not be vented before use.

INSTRUCTIONS FOR USE

Proper subcutaneous (under the skin) injection is essential to decrease the pain and bruising at the injection site.

Preparing the injection site

The recommended injection site is in the fat of the abdomen. This must be at least 5 cm from the navel to the outside and to one side or the other.



For injection, wash your hands. Clean (without rubbing) the chosen injection site with an alcohol swab. Choose a different site for each injection of the abdomen.



Technique for subcutaneous injection (prefilled syringes):

Carefully remove needle cap by firmly pulling it straight out and discard. **(DO NOT EXPEL THE AIR BUBBLE)**



Sit or lie in a comfortable position. Take a fold of skin (fat from the abdomen) between your thumb and forefinger. Insert the full length of the needle vertically into the skin fold (90° angle)



Press down on the plunger with your thumb until the syringe is empty and the abdominal wall remains folded until the injection is done. **(DO NOT RUB THE INJECTION SITE)**



Remove the syringe from the injection site. Throw the syringe away immediately in the nearest sharps collector.



How much to use

The usual dose is:

- To reduce the risk of blood clots in the veins (thromboembolic disorders) One subcutaneous (subcutaneous) injection of 2000 anti-Xa IU (0.2ml) or 4000 anti-Xa IU (0.4ml) daily.
- In order to prevent blood clots in the veins that may occur after some operations, it is possible that an initial injection is given several hours before the operation.
- In the orthopedic surgery has been found advantageous to initial therapy with 4000 anti-Xa IU once daily to continue for 4-5 weeks.
- For blood clots in the veins occur in bedridden patients, the recommended dose of Clexane is one subcutaneous injection of 4000 anti-Xa IU per day. Treatment is prescribed for a minimum of 6 days, and continued until you can step back (with a maximum of 14 days).

Treatment with Clexane is usually prescribed for an average period of 7 to 10 days. A longer duration of treatment may be indicated in some patients.

- To treat blood clots

Treatment of blood clots in the veins (deep vein thrombosis) with or without pulmonary embolism:

The dosage:

- a subcutaneous injection of 100 anti-XaIU Clexane per kg of body weight every 12 hours (2 times per day) for 10 days.

In angina (unstable angina) or non-Q-wave heart attack:

The recommended dose is 100 anti-Xa IU per kg of body weight administered subcutaneously every 12 hours, in combination with acetylsalicylic acid (75 to 325 mg per day) by the oral route.

In acute myocardial infarction with ST-segment elevation (STEMI):

The recommended dose is a single intravenous injection of 3000anti-Xa IU, together with a subcutaneous injection of 100 anti-Xa IU/kg of body weight. This is followed by a subcutaneous administration of 100 anti-Xa IU/ kg of body weight every 12 hours.

(With a maximum dose of Clexane 10000 anti-Xa IU for each of the first two subcutaneous administrations, followed by subcutaneous administration of 100 anti-Xa IU/ kg of body weight for the following doses). For the dose in patients aged 75 years, see section "Elderly".

The recommended treatment duration is 8 days or until you leave the hospital, if the hospitalization period is less than 8 days.

For patients subsequently treated with coronary angioplasty: Depending on when you were last given Clexane, your doctor may decide to give an additional dose of Clexane before a coronary angioplasty operation. This is by injection into your vein (intravenous).

- To prevent blood clots forming in the tubes of your dialysis machine in hemodialysis
An initial dose of 100 anti-Xa IU/ kg of body weight will be added to the tube leaving the body (arterial line) at the beginning of the session. This dose is normally sufficient for a hemodialysis session for 4 hours. However, your

doctor may give you a further dose of maximum of 100 anti-Xa IU/kg if necessary.

If you have a high risk of bleeding (eg in pre-and postoperative dialysis or evolutionary haemorrhagic syndrome), the dialysis treatments may be performed at a lower dose (50 anti-Xa IU/ kg for double vascular access or 75 anti-Xa IU/ kg in single vascular access).

Children

The safety and effectiveness of Clexane in children have not yet been demonstrated.

Elderly

Treatment of acute myocardial infarction with ST-segment elevation: Do not use single intravenous injection in patients aged 75 years. Use a subcutaneous administration of 75anti-Xa IU/ kg of body weight every 12 hours (with a maximum dose of 7500 anti-Xa IU Clexane for each of the first two subcutaneous administrations, followed by subcutaneous administration of 75 anti-Xa IU/ kg of body weight for the following doses) .

Renal insufficiency

If you have a reduced effect exhibits of your kidneys, your doctor may reduce the dose of Clexane to minimize the risk of bleeding.

When to use it

Using your medicine at the same time each day will have the best effect. It will also help you remember when to use the medicine.

If you are not sure when to use it, ask your doctor or pharmacist.

How long to use it

Your doctor will tell you how long your Clexane should be administered.

If you forget to use it

Do not use a double dose to make up for a forgotten dose.This may increase the chance of getting an unwanted side effect.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or

anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

Things you must do

Using Clexane may affect the results of some of the blood tests. If you are going to have a blood test, it is important to tell your doctor you are having Clexane.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop using Clexane (until your doctor decides to stop them or change the dosage) without checking with your doctor. If you do so, you could get a blood clot which can be very dangerous.

Things to be careful of

Driving and using machines

Clexane has no influence on the ability to drive and use machines.

Side Effect

- Bleeding a lot from a wound
- A painful rash of dark red spots under the skin which do not go away when you put pressure on them. You may also notice pink patches on your skin. These are more likely to appear in the area you have been injected with Clexane
- If you have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- If you have had a spinal puncture or a spinal anaesthetic and notice tingling, numbness and muscular weakness, particularly in the lower part of your body.

- You bruise more easily than usual. This could be because of a blood problem (thrombocytopenia)
- You have pain, swelling or irritation in the area you have been injected with Clexane. This normally gets better after a few days
- Changes in the results of blood tests done to check how your liver is working. These usually go back to normal after you stop having Clexane
- Changes in the potassium levels in your blood.
- If Clexane is used for a long period of time, it may increase the risk of you getting a condition called 'osteoporosis'. This is when your bones are more likely to break

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

Ask your doctor or pharmacist to answer any questions you may have.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Clexane

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

Keep this medicine in a safe place where children cannot see or reach it. Do not use Clexane after the expiry date which is stated on the outer packaging. Store below 25°C. Do not freeze pre-filled syringes.

Disposal

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 to protect the environment.

Product Description

What it looks like

Boxes of clear, colorless to yellow solution in 2 pre-filled syringes for subcutaneous or intravenous injection.

Ingredients:

- The pre-filled syringes contain 2000 anti-Xa IU enoxaparin sodium (0.2 ml), 4000 anti-Xa IU enoxaparin sodium (0.4 ml), 6000 anti-Xa IU enoxaparin sodium (0.6 ml) as active substance
- The solvent for Clexane pre-filled syringes is water for injection.

MAL Numbers:

Clexane 2000/0.2ml anti-XA IU (Pre-filled Syringe for Injection) MAL19950380A

Clexane 4000/0.4ml anti-XA IU (Pre-filled Syringe for Injection) MAL19950379A

Clexane 6000/0.6ml anti-XA IU (Pre-filled Syringe for Injection) MAL19973597A

Manufacturer and Product Registration Holder

Manufacturer

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Product Registration Holder

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