The name of your medicine is Clexane® Syringes 100mg/ml Solution for Injection (enoxaparin sodium). This belongs to a group of medicines called Low Molecular Weight Heparins.

Clexane works in two ways, 1) Stopping existing blood clots from getting any bigger. This helps your body to break them down and stop them causing you harm. 2) Stopping blood clots forming in your blood.

Clexane can be used to:
- Treat blood clots that are in your blood
- Stop blood clots forming in your blood in the following situations:
  - Unstable angina (where not enough blood gets to your heart)
  - Symptoms of heart attack called NSTEMI
  - After an operation or long periods of bed rest due to illness
  - Blood clots forming in the tubes of your dialysis machine (used for people with kidney problems)

2. Before you use Clexane

Do not use this medicine and tell your doctor, pharmacist or nurse if:
- You are allergic (hypersensitive) to enoxaparin sodium or any of the other ingredients of Clexane (listed in Section 6: Further information).
- You have had a stroke
- You have had a stroke in your eyes or brain
- You have had an operation or have had any surgery
- You have a problem with the blood vessels in the back of your eye (retinopathy)
- You are pregnant and are at high risk of losing the baby
- You have liver or kidney problems
- You have had a heart valve fitted
- You have ever had bruising and bleeding caused by the medicine ‘heparin’
- You have ever had a stroke
- You have ever had a stomach ulcer
- You have recently had an operation (or trauma to) your eyes or brain
- You are a diabetic or have an illness known as ‘diabetic retinopathy’ (problems with the blood vessels in the eye caused by diabetes)
- You have any problems with your blood
- You have raised blood potassium levels (hyperkalaemia)
- You are overweight
- You have had a previous blood clot
- You are elderly (over 65 years old) and especially if you are 75 years old or over
- You are underweight or overweight. Overweight patients are at higher risk for thromboembolism, the blocking of a blood vessel.
- You have liver or kidney problems
- You have high blood pressure
- You have any high blood levels of creatinine
- You have any problems with your blood
- You have a problem with the blood vessels in your backbone (spinal

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 affecting your blood.

Operations and anaesthetics
If you have a history of spinal surgery or spinal deformity or if you are going to have an operation or an anaesthetic that requires epidural or spinal anaesthetic is used, tell your doctor that you are using Clexane.

Pregnancy and breast-feeding
Talk to your doctor before you use 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.

How much will be given to you
Your doctor will have decided how to give you. The amount of Clexane given to you will depend on the reason it is being given and your condition.

How will be given to you
Your doctor, pharmacist or nurse will tell you how much you are to be given. This amount is usually enough for a 4 hour session.

3. How to use Clexane

Instructions on injecting yourself with Clexane:

1) Treating blood clots that are in your blood
- The usual dose is 1.5mg for every kilogram of your weight, each day.
- This will usually be given for at least 5 days.

2) Stopping blood clots forming in your blood in the following situations:
   a) Unstable angina or NSTEMI type of heart attack
      - The usual dose is 1.5mg for every kilogram of your weight, every 12 hours
      - Clexane will usually be given for 2 to 8 days. Your doctor will normally ask you to take aspirin as well
   b) After an operation or long periods of bed rest due to illness
      - The usual dose is 20mg or 40mg each day. The dose will depend on how likely you are to develop a clot
      - If you have a low to medium risk of getting a clot, you will be given 20mg of Clexane each day, if you are going to have an operation, your first injection will usually be given 2 hours before your operation
      - If you have a higher risk of getting a clot, you will be given 40mg each day, if you are going to have an operation, your first injection will usually be given 12 hours before your operation
      - If you are bedridden due to illness, you will normally be given 40mg of Clexane each day for 6 to 14 days
   c) Treating blood clots forming in the tubes of your dialysis machine
      - The usual dose is 1 mg for every kilogram of your weight
      - Clexane 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 0.5 to 1mg for every kilogram of your weight if necessary

Children: Clexane is not recommended for use in children.

How to give yourself an injection of Clexane
If you are able to give Clexane to yourself, your doctor or nurse will have told 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.

Before injecting yourself with Clexane

Check the expiry date on the medicine. Do not use the medicine if the date is expired.

Check the syringe is not damaged and the medicine in it is clear. If not, use another syringe.

Check you know how much you are going to inject

Check your abdomen to see if the last injection caused any reddening, 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 you inject. Inject the needle into the right side of your stomach. Clexane should be injected just under the skin but not in the belly button or any scar tissue (at least 5 cm away from any scar).

Injections on injecting yourself with Clexane:
1) Wash your hands and the area that you will inject with soap and water. Dry them.
2) Check the expiry date on the medicine. Do not use the medicine if the date is expired.
3) Check the syringe is not damaged and the medicine in it is clear. If not, use another syringe.
4) Check you know how much you are going to inject
5) Check your abdomen to see if the last injection caused any reddening, change in skin colour, swelling, oozing or is still painful, if so talk to your doctor or nurse
6) Decide where you are going to inject the medicine. Change the place where you inject each time you inject. Inject the needle into the right side of your stomach. Clexane should be injected just under the skin but not in the belly button or any scar tissue (at least 5 cm away from any scar).
2) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A change chair, recliner, or bed propped up with pillows is ideal.
3) Choose an area on the right or left side of your stomach, it should be at least 5 centimetres away from your belly button and out towards your sides.

Remember: Do not inject yourself within 5 centimetres of your belly button or around existing scars or bruising. Change the place where you inject between the left and right sides of your stomach, depending on the area you were last injected.

Cut the rubber seal off the needle cap from the Clexane syringe. Do not bend the needle. Throw away the cap. The syringe is pre-filled and ready to use.

Do not... Don't try to cut off the needle yourself in order 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).
Hold the syringe with the needle pointing downwards and tap so as the air bubble rises to the top (nearest the plunger). If your dose is less than the content of the syringe, follow the instructions provided by your Health Care Practitioner. Twist the plunger to see graduations, if required.

5) Hold the syringe in the hand you write with (like a pencil) and with your other hand 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.

6) Hold the syringe so that the needle is pointing downwards (vertically at a 90º angle). Insert the full length of the needle into the skin fold

7) Press down gently but firmly on the plunger all the way until you hear a click. This will send the medication into the fatty tissue of the skin. Make sure you hold the skin fold throughout the injection.

8) Remove the needle by pulling it straight out. A protective sleeve will automatically cover the needle as you withdraw it. You can now get off the skin fold. Note: The safety system allowing release of the protective sleeve, can only be activated when the syringe has been emptied by pressing the plunger all the way down.

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

Do not... Do not use syringes if its protective sleeve into the sharp pin provided. Close the container lid tightly and place the container out of reach of children.
When the container is full, give it to your doctor or home care nurse for disposal. Do not put it in the household rubbish.

If you have more Clexane than you should If you think that you have used too much or too little Clexane, tell your doctor, nurse or pharmacist immediately, even if you have no reason to. If you accidentally inject or swallow Clexane, take them to a hospital casualty department straight away.

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

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

4. Possible side-effects
Like all medicines, Clexane can cause side-effects, although not everybody gets them.
Tell a nurse or doctor straight away if you notice any of the following side-effects:

Very common (affects more than 1 in 10 people)

- Bleeding a lot from a wound.
- You have noticed any of the following side effects:

Rare (affects less than 1 in 100 people)

- A rash or rash with red spots on your skin
- You have noticed any of the following side effects:

Common (affects 1 to 10 people in a 100)

- A painfull rash of dark red spots on 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.
- You have noticed any of the following side effects:

Uncommon (affects 1 to 10 people in a 1,000)

- A sudden severe headache. This could be a sign of bleeding in continuing:
- A feeling of tenderness and swelling in your stomach. You may have bleeding in your stomach.
- You have noticed any of the following side effects:

Rare (affects less than 1 in 1,000 people)

- If you have an allergic reaction. The signs may include:

Other side effects that you should discuss with your doctor if you are concerned about them:

- Very common (affects more than 1 in 10 people)
- You bruise more easily than usual. This could be because of a bleeding problem (thrombocytopenia). You have noticed any of the following side effects:
- You have pain, swelling or irritation in the area you have been injected with Clexane. This normally gets better after a few days.
- Rare (affects less than 1 in 1,000 people)
- If you have a mechanical heart valve, treatment with Clexane might not be sufficient to prevent blood clots. You may notice that you have difficulty breathing, tiredness or difficulty exercising, chest pain, numbness, feeling of sickness or loss of consciousness. This could be due to a blood clot on the heart.

Bleeding a lot from your limbs or gums. This could be a sign of continuing:
- You have pain or swelling in a limb.

Changes in the potassium levels in your blood. This is more likely if you have had a stroke or in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test.

Frequency unknown

- If Clexane is used for 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.
- Anaphylactic reactions including shock.
- Headache.
- Anaemia - a blood disorder.
- Bleomina - a blood disorder.
- Alopecia - hair loss.
- Liver injury, both hepato-cellular & cholestastic.

Reporting of side effects
If you have any side effects, tell your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. Reports may be made by following the links to the online reporting option accessible from the IMI homepage, or by completing the downloadable report form accessible from the IMI website, which can be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
Pharmacovigilance Section, Irish Medicines Board, Kevin O’Malley House, Earlsfort Centre, Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website www.imb.ie
Email: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of medicines.

5. How to store and dispose of Clexane

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

Keep in their box, deep them out of reach and sight of children. Do not keep the syringes if your doctor decides to stop treatment. Return them to your pharmacist who will arrange for their safe disposal.

Each syringe contains a single dose. Any unused product should be discarded. Remember that injections are only for you. Only a doctor may prescribe for you.

Never give them to other people. They may harm other people even if their symptoms appear the same as yours.

Medicine should not be disposed of via wastewater or household waste. If you are using this medicine at home you will be given a container (solution bag or sharp bin) to put any unused or used syringes to your doctor, nurse or pharmacist for disposal. This measure will help to protect the environment.

6. Further Information

What Clexane contains
The active ingredient in the Clexane Syringes is enoxaparin sodium. Clexane Syringes contain 20mg (equivalent to 2,000 IU anti-Xa activity) enoxaparin sodium per 0.2ml or 45mg (equivalent to 4,000 IU anti-Xa activity) enoxaparin sodium per 0.4ml. The other ingredients is water for injection. Clexane Syringes are packed, into boxes of 10 prefilled syringes.

Check the expiry date on the pack before you use it. It should be a blood clot on the heart.


Clexane Syringes contain 100mg/ml Solution for Injection
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Leaflet date: 10.04.2014
Clexane® is a registered trademark of Aventis Pharma.