

PACKAGE LEAFLET: INFORMATION FOR THE USER

Clexane[®] Syringes 100mg/ml Solution for Injection

Enoxaparin sodium

Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Clexane is and what it is used for
2. Before you use Clexane
3. How to use Clexane
4. Possible side-effects
5. How to store Clexane
6. Further information

1. WHAT CLEXANE IS AND WHAT IT IS USED FOR

The name of your medicine is Clexane Syringes 100mg/ml Solution for Injection (called Clexane in this leaflet). Clexane contains a medicine called 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) or a type of heart attack called NSTEMI
 - After an operation or long periods of bed rest due to illness
 - Stop blood clots forming in the tubes of your dialysis machine (used for people with kidney problems)

2. BEFORE YOU USE CLEXANE

Do not have 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). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You are allergic to heparin or other Low Molecular Weight Heparins such as tinzaparin or dalteparin
- 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 an infection in your heart
- You have jaundice (yellowing of the skin or whites of the eyes)
- You have a problem with the blood vessels in the back of your eyes (retinopathy)
- You are pregnant and are at high risk of losing the baby

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before using Clexane.

! Take special care with Clexane

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

- You have high blood pressure
- 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 on (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 underweight or overweight. Overweight patients are at higher risk for thromboembolism, the blocking of a blood vessel due to a blood clot
- You are elderly (over 65 years old) and especially if you are aged over 75 years old

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using Clexane.

Taking or using 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.

In particular, do not use this medicine and tell your doctor if:

You are using the medicine called heparin 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 as a blood replacer
- Ibuprofen, diclofenac, ketorolac or other medicines -used to treat pain and swelling in arthritis and other illnesses
- Prednisolone, dexamethasone or other medicines - used to treat asthma, rheumatoid arthritis and other conditions
- 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 have a history of spinal surgery or spinal deformity or 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 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.

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.

3. HOW TO USE CLEXANE

Using this medicine

- Before you use Clexane your doctor or nurse may carry out a blood test
- While you are in hospital your doctor or nurse will normally give you Clexane. This is because it needs to be given as an injection
- When you go home you may need to continue to use Clexane and give it to yourself (see below instructions on how to do this)
- Clexane is usually given by injection underneath the skin (subcutaneous)

If you are not sure why you are receiving Clexane or have any questions about how much Clexane is being given to you, speak to your doctor, pharmacist or nurse.

How much will be given to you

- Your doctor will decide how much to give you. The amount of Clexane given to you 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

1) Treating blood clots that are in your blood

- The usual dose is 1.5mg for every kilogram of your weight, each day
- Clexane 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 amount is 1mg for every kilogram of 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 bedrest 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

3) Stop 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

Further detailed information including dosing charts is available to Healthcare Professionals in the Summary of Products Characteristics available from the HPRa at www.hpra.ie.

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 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 Clexane

- 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 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. Clexane 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)

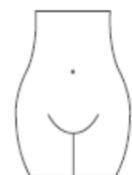
Instructions on injecting yourself with Clexane:

- 1) Wash your hands and the area that you will inject with soap and water. Dry them.



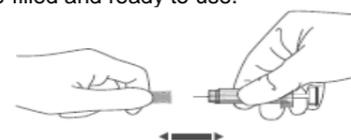
- 2) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. A lounge chair, recliner, or bed propped up with pillows is ideal.

- 3) 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.



Remember: Do not inject yourself within 5 centimetres 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 were last injected.

- 4) Carefully pull off the needle cap from the Clexane syringe. Throw away the cap. The syringe is pre-filled and ready to use.



Do not press on the plunger before injecting yourself 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 90° angle). Insert the full length of the needle into the skin fold



- 7) Press down gently but firmly on the plunger, ALL OF THE WAY. This will send the medication into the fatty tissue of the stomach. 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. You can now let go of 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.

- 9) Drop the used syringe with its protective sleeve into the sharps bin 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 use 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 signs of a problem. If a child accidentally injects or swallows 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 you are using 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

Common (affects 1 to 10 people in a 100)

- 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

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

- 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 inside your stomach

Rare (affects less than 1 in a 1000 people)

- 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. Also if you lose control over your bladder or bowel (so you cannot control when you go to the toilet)

Tell a nurse or doctor as soon as possible if you notice any of the following side-effects:

Common (affects 1 to 10 people in 100)

- 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

Rare (affects less than 1 in a 1000 people)

- If you have a mechanical heart valve, treatment with Clexane might not be sufficient to prevent blood clots. You may notice that that you have difficulty breathing, tiredness or difficulty exercising, chest pain, numbness, feeling sick or loss of consciousness. This could be due to a blood clot on the heart valve

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)

- 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

Rare (affects less than 1 in 1000 people)

- Changes in the potassium levels 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

Frequency unknown

- 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 bones are more likely to break.
- Anaphylactic reactions including shock

- Headache
- Anaemia – a blood disorder
- Alopecia – hair loss
- Liver injury, both hepatocellular & cholestatic

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 via

HPRAs Pharmacovigilance,

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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

5. HOW TO STORE AND DISPOSE OF CLEXANE

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 carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not store in a refrigerator or freezer.

Each syringe is for single use only. Any unused product should be discarded.

Medicines should not be disposed of via wastewater or household waste. If you are using this medicine at home you will be given a container (a sharps bin) to use for disposal. Return the sharps bin or any used or unused syringes to your doctor, nurse or pharmacist for disposal.

These measures will help to protect the environment.

6. FURTHER INFORMATION

What Clexane contains

Each Clexane Syringe contains 100mg of enoxaparin sodium per ml.

Each 40mg pre-filled syringe contains 40mg (4,000 IU anti-Xa activity) of the active substance, enoxaparin sodium in 0.4ml water for injections.

What Clexane Pre-filled Syringes looks like and contents of the pack

Clexane is a clear solution in a Type I glass pre-filled syringe fitted with an injection needle and needle cap, it is supplied in packs of 10 syringes.

Product procured from within the EU and repackaged by the Parallel Product Authorisation Holder

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Manufacturer

Sanofi Winthrop Industrie, Boulevard industriel. Zone industrielle (Le trait), 76580 –France

PPA Number: 465/251/1

Clexane is a registered trademark of MAY & BAKER LIMITED.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Date leaflet prepared by PCO Manufacturing: 06/2014