**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S4

CLEXANE® 20 (Solution for injection in prefilled syringes)

CLEXANE® 40 (Solution for injection in prefilled syringes)

CLEXANE® 60 (Solution for injection in prefilled syringes)

CLEXANE® 80 (Solution for injection in prefilled syringes)

CLEXANE® 100 (Solution for injection in prefilled syringes)

CLEXANE® 300 (Solution for injection)

Enoxaparin sodium

Sugar free

**Read all of this leaflet carefully before you are given CLEXANE**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CLEXANE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

## 1. What CLEXANE is and what it is used for

The active substance is enoxaparin sodium.

CLEXANE is one of a group of medicines called low molecular weight heparins (LMWH). These medicines work by reducing blood clotting activity.

CLEXANE is used in a number of medical conditions. It is used to:

- Treat blood clots in veins
- stop blood clots from forming when you have certain types of heart disease (e.g. angina and heart attacks), when used with aspirin
- prevent blood clots forming after an operation, during hospitalisation or extended bed rest or during purification of the blood by an artificial kidney (haemodialysis) machine.

## 2. What you need to know before you use or receive CLEXANE

**Do not use or receive CLEXANE:**

- If you are hypersensitive (allergic) to:
  - enoxaparin sodium
  - heparin, its derivatives including other low molecular weight heparins such as nadroparin or dalteparin
  - benzyl alcohol (multiple vial dose only – see section 6).

  Signs of an allergic reaction can include swelling of the face, lips or tongue, wheezing or troubled breathing, skin rash, itching hives, blisters or peeling skin.
- if you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) in your blood within the past 100 days
- if you have antibodies against enoxaparin in your blood

- if you are bleeding heavily
- if you have a condition with a high risk of bleeding such as:
    - recent bleeding stroke and disorders of the brain
    - blood disorders that can cause bleeding
    - low blood platelet counts
    - stomach ulcer
    - bacterial infections in your heart (endocarditis)
    - severe or uncontrolled high blood pressure.

Do not use CLEXANE in children as the safety and efficacy has not been established for this use.

**Warnings and precautions**

Clexane Syringes should not be interchanged with other 'low molecular weight heparins' such as nadroparin or dalteparin. This is because they are not exactly the same and do not have the same activity and instructions for use.

Tell your doctor or health care provider before you use or receive CLEXANE:

- If you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets)
- if you have had a prosthetic heart valve fitted
- if you have endocarditis (an infection of the inner lining of the heart)
- if you have a history of gastric ulcer
- if you have impaired blood clotting
- if you have had a recent stroke
- if you have high blood pressure

- if you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- if you have had an operation recently on your eyes or brain
- if you are currently using medicines which affect bleeding (see section 2 - Other medicines and CLEXANE)
- if you are elderly (over 65 years old) and especially if you are over 75 years old
- if you have kidney problems
- if you have liver problems
- if you are underweight or overweight
- if you have any problem with your spine, spinal deformity 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 CLEXANE.

Special care should be taken with CLEXANE:

- If you experience bleeding from any site, tell your doctor immediately
- if your doctor is planning for you to have any of the following, tell your doctor that you are using CLEXANE:
  - a heart procedure.
  - an anaesthetic injection in your back (spinal or epidural anaesthesia or lumber puncture). Also inform your doctor immediately if any of the following happens after you have had the procedure: pain in the middle of your back (midline back pain); numbness and weakness in your legs (sensory and motor deficits) or problems having a bowel movement or passing urine.

**Children and Adolescents**

The safety and efficacy of CLEXANE in children has not been established.

**Other medicines and CLEXANE**

Always tell your health care professional if you are taking any other medicine (this includes complementary or traditional medicines).

Some medicines and CLEXANE may interfere with each other. These include:

- Medicines or substances used to prevent and treat blood clots (such as ticlopidine, clopidogrel, thrombolytics and anticoagulants (e.g. warfarin (used for thinning the blood))
- dextran 40 (used as a blood replacer)
- medicines containing aspirin or salicylates (used as a painkiller or to stop blood clots from forming)
- medicines used to treat pain and swelling in arthritis and other conditions, such as oral non-steroidal anti-inflammatory medicines (including ibuprofen, ketorolac and diclofenac)
- corticosteroids such as prednisolone or dexamethasone used to treat asthma, rheumatoid arthritis and other conditions.

**Pregnancy and Breastfeeding**

If you are pregnant or breastfeeding your baby, think that you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice.

The safety of CLEXANE during pregnancy or breastfeeding has not been established.

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.

If you are receiving CLEXANE, you should not breastfeed your baby.

**Driving and using machines**

CLEXANE should not affect your ability to drive or operate machines.

## 3. How to use or receive CLEXANE

Do not share medicines prescribed for you with any other person.

Your doctor will decide what dose you will use or receive. This depends on your condition and other factors, such as your weight.

CLEXANE is usually given by an injection under the skin or into the tubing of the dialysis machine. The recommended site for injection is the stomach area. A different injection site will be used for each injection. You should not rub the injection site after administration. CLEXANE may be given by your doctor, nurse or yourself. Your doctor will tell you how you will be given your injection.

Do not administer CLEXANE by the intramuscular route.

CLEXANE can also be given by an injection into a vein. This will be done in hospital by your doctor or nurse.

If you have the impression that the effect of CLEXANE is too strong or too weak, tell your doctor or pharmacist.

### If you receive or use more CLEXANE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

### If you forget to take a dose or if you missed a dose of CLEXANE

Do not use or receive a double dose to make up for forgotten individual doses.

## 4. Possible side effects

CLEXANE can have side effects.

Not all side effects reported for CLEXANE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using or receiving CLEXANE, please consult your health care provider for advice.

If any of the following happens, stop using CLEXANE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Signs of a severe allergic reaction (such as rash, difficulty breathing or swallowing, swelling of the face, lips, mouth, throat or eyes)
- bleeding that does not stop by itself
- signs of too much bleeding such as being very weak, tired, pale, or dizzy with headache or unexplained swelling. CLEXANE may cause severe bleeding. This may be life-threatening and in some cases the bleeding may not be obvious.
- 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to CLEXANE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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 (blood clot in the lung)

- 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 to perform a blood test to check your platelet count.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

**Frequent:**

- Bleeding
- decreased red blood cell count
- you bruise more easily than usual – this could be because of a blood problem with low platelet counts
- high platelet counts in the blood
- allergic reaction
- headache
- increases in liver enzymes
- itchy or red skin or rash (hives, urticaria)
- bleeding, bruising, pain, swelling, inflammation or itching at the injection site.

**Less frequent:**

- An increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
- tingling, numbness and muscular weakness (particularly in the lower part of your body) or loss of control over your bladder or bowel when you have had a spinal puncture or a spinal anaesthetic
- yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem
- large red irregularly shaped skin lesions with or without blisters

- hair loss
- painful red or purple spots, swelling and ulcers of the skin (vasculitis of the skin), or dying of skin cells at injection site (skin necrosis) usually occurring at the injection site. Treatment with CLEXANE must be discontinued.
- osteoporosis (a condition where your bones are more likely to break) after long-term use (longer than 3 months)
- skin irritation (local irritation)
- hard mass or lump at the injection site
- increased potassium in your blood.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**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 report any side effects directly to Sanofi's Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CLEXANE.

**5. How to store CLEXANE**

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not freeze or refrigerate.

Prefilled syringes: discard any unused portion.

Multidose vial: Do not use the multidose vial for more than 28 days after first use.

Do not use after the expiry date stated on the pack.

For the multi dose vial, keep the vial in the outer carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Return all unused medicine to your pharmacist.

## 6. Contents of the pack and other information

### What CLEXANE contains

The active substance is enoxaparin sodium.

Each prefilled syringe contains:

CLEXANE 20: 20 mg enoxaparin sodium per 0,2 ml

CLEXANE 40: 40 mg enoxaparin sodium per 0,4 ml

CLEXANE 60: 60 mg enoxaparin sodium per 0,6 ml

CLEXANE 80: 80 mg enoxaparin sodium per 0,8 ml

CLEXANE 100: 100 mg enoxaparin sodium per 1,0 ml

The other ingredient is water for injections.

The multidose vial contains:

**CLEXANE 300**: 300 mg enoxaparin sodium per 3 ml

The other ingredients are benzyl alcohol (preservative) and water for injections.

### What CLEXANE looks like and contents of the pack

Solution for injection in prefilled syringes: A clear, colourless to pale yellow solution.

CLEXANE 20: 0,2 ml solution for injection in a 0,5 ml prefilled syringe with a safety device in packs of 6 or 10.

CLEXANE 40: 0,4 ml solution for injection in a 0,5 ml prefilled syringe with a safety device in packs of 6 or 10.

CLEXANE 60: 0,6 ml solution for injection in a 1 ml prefilled syringe with a safety device in packs of 6 or 10.

CLEXANE 80: 0,8 ml solution for injection in a 1 ml prefilled syringe with a safety device in packs of 6 or 10.

CLEXANE 100: 1 ml solution for injection in a 1 ml prefilled syringe with a safety device in packs of 6 or 10.

Solution for injection (in a multidose vial): A clear, colourless to slightly yellow solution, practically free from particles.

CLEXANE 300: 3 ml solution for injection in a single multidose vial.

**Holder of Certificate of Registration**

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