

PATIENT INFORMATION LEAFLET

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 or pharmacist.
- CLEXANE has been prescribed for you personally.

SCHEDULING STATUS:

S4

NAME OF MEDICINAL PRODUCT:

CLEXANE® 20 (Injection)

CLEXANE® 40 (Injection)

CLEXANE® 60 (Injection)

CLEXANE® 80 (Injection)

CLEXANE® 100 (Injection)

CLEXANE® 300 (Injection)

WHAT CLEXANE CONTAINS

The active ingredient in CLEXANE 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 only other ingredient in the prefilled syringes is: water for injection.

The multidose vial contains:

CLEXANE 300: 300 mg enoxaparin sodium per 3 ml.

The other ingredients in the multidose vial are: benzyl alcohol (preservative) and water for injection.

WHAT CLEXANE IS USED FOR

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
- treat 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).

Ask your doctor if you have any questions about why CLEXANE has been prescribed for you.

CLEXANE is only available with a doctor's prescription.

BEFORE YOU USE CLEXANE

You should not receive CLEXANE if you have or have ever had:

- an allergy to CLEXANE, heparin or its derivatives including other LMWHs or benzyl alcohol. Some signs and symptoms 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
- active bleeding from any site
- a major bleeding disorder or blood clotting problem (such as excessive bleeding), including certain cerebrovascular disorders or hereditary or heparin-associated blood disorders
- stomach or bowel problems such as ulcers or ulcerative colitis
- bacterial infections in your heart
- severe or uncontrolled high blood pressure.

Do not give CLEXANE to a child, pregnant or lactating women or patients with prosthetic heart valves, as safety and efficacy has not been established.

Take special care with CLEXANE:

It is very important to tell your doctor that you are using CLEXANE if your doctor is planning for you to have:

- an anaesthetic injection in your back (spinal or epidural anaesthesia)
- a heart procedure

If you need to have an anaesthetic injection in your back (spinal or epidural anaesthesia) while using CLEXANE, this should be done in a hospital. Tell your doctor immediately if any of the following happens after an anaesthetic injection in your back:

- pain in the middle of your back (midline back pain)
- numbness and weakness in your legs (sensory and motor deficits)
- intestinal problems and problems in passing urine.

Tell your doctor immediately if you experience bleeding from any site.

Tell your doctor if you have or have had any of the following medical conditions:

- a history of stomach ulcers (see 'You should not receive CLEXANE')
- kidney or liver disease
- high blood pressure (see 'You should not receive CLEXANE')
- diabetic related eye disease
- recently undergone brain, spinal or eye surgery
- impaired blood clotting
- an artificial heart valve (see 'You should not receive CLEXANE')
- a recent stroke.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby while taking CLEXANE, please consult your doctor, pharmacist or other health care professional, for advice.

It is not recommended to take CLEXANE if you are pregnant or breastfeeding your baby.

Taking other medicines with CLEXANE:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CLEXANE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

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

- medicines or substances used to prevent and treat blood clots (such as dextran 40, ticlopine, clopidogrel, thrombolytics and anticoagulants)
- medicines containing aspirin or salicylates

- medicines used to treat inflammatory diseases, such as oral non-steroidal anti-inflammatory medicines (including ketorolac and diclofenac) or corticosteroids.

HOW TO USE CLEXANE

Your doctor will decide what dose you will 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 receive or use more CLEXANE than you should:

If you have accidentally injected too much of your medicine, contact your doctor or pharmacist as soon as possible. If neither is available, seek help at the nearest hospital or poison control center.

POSSIBLE SIDE EFFECTS

Not all side effects reported for CLEXANE are included in this leaflet. Should your general health worsen while taking CLEXANE, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop using CLEXANE and tell your doctor immediately:

- painful itchy red/purple rash at the injection site
- difficulty in breathing, symptoms of hayfever, feeling faint, itching hives, blisters or other symptoms of allergy
- bleeding (including nose bleeds or prolonged bleeding from cuts), bruising more easily than normal, red or dark brown urine, red or black bowel motions
- numbness (paralysis), problems with coordination, dizziness, tiredness, light-headedness, blurred vision, confusion or difficulty speaking

- severe abdominal, chest pain and headache
- nausea, diarrhoea, fever
- swelling of the hands, ankles or feet
- a fine widespread rash, especially noticeable on your mouth or eyes or sudden onset of white or blue colour in fingers or toes suggesting poor blood supply.

Tell your doctor if you notice any of the following and they worry you:

- pain, bruising or irritation at the injection site after **CLEXANE** has been given
- hard inflamed nodules at the injection site
- itchy red rash at the injection site
- bleeding at the injection site
- itchy skin.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of **CLEXANE**. Ask your doctor, pharmacist or other healthcare professional for more information.

STORAGE AND DISPOSAL OF CLEXANE

KEEP OUT OF SIGHT AND REACH OF CHILDREN.

Store at or below 25 °C.

Do not freeze or refrigerate. Discard any unused portion.

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

Do not dispose of unused medicine in drains or sewerage systems.

Return all unused medicine to your pharmacist.

PRESENTATION OF CLEXANE

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

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

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

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

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

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

IDENTIFICATION OF CLEXANE:

CLEXANE 20: Clear, colourless to pale yellow solution.

CLEXANE 40: Clear, colourless to pale yellow solution.

CLEXANE 60: Clear, colourless to pale yellow solution.

CLEXANE 80: Clear, colourless to pale yellow solution.

CLEXANE 100: Clear, colourless to pale yellow solution.

CLEXANE 300: Clear and practically free from particles, colourless to slightly yellow solution.

REGISTRATION NUMBERS

CLEXANE 20: A39/8.2/0079

CLEXANE 40: X/8.2/42

CLEXANE 60: 31/8.2/0480

CLEXANE 80: 31/8.2/0481

CLEXANE 100: 31/8.2/0482

CLEXANE 300: 32/8.2/0122

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

sanofi-aventis south africa (pty) ltd

2 Bond Street

Midrand, 1685

South Africa

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

26 October 2012