**Package leaflet: Information for the user**

Multi-dose Vial 30,000 IU (300 mg)/3 mL

- **Solution for injection**
- **Clexane Multidose Vial contains the active substance enoxaparin sodium.**

**What is in this leaflet?**

1. What Clexane Multidose Vial is and what it is used for
2. How to use Clexane Multidose Vial
3. How much will be given to you
4. How to use Clexane Multidose Vial
5. Use in children and adolescents
6. Tests and checks
7. Use in children and adolescents
8. Other medicines Clexane Multidose Vial should not be taken with
9. How to use Clexane Multidose Vial
10. Stopping blood clots from forming in your blood

**What is Clexane Multidose Vial and is it used for?**

- **Clexane Multidose Vial** is a medicine used to prevent blood clots from forming in the blood and to treat blood clots that are already present in the blood.

**How much will be given to you?**

- **Your doctor or nurse will normally give you Clexane Multidose Vial.** This is because it needs to
- **Your doctor will decide how long you should receive Clexane Multidose Vial.**

**How much will be given to you?**

- **The usual dose is 100 IU (1 mg) for every kilogram of your bodyweight.**

**When can you stop using Clexane Multidose Vial?**

- **If you are going to have a spinal or lumbar puncture, or an operation where an epidural or spinal anaesthesia is used, tell your doctor or pharmacist that you are using Clexane Multidose Vial.**

**Use in children and adolescents**

- **Use Clexane Multidose Vial with caution in children.*

**Other medicines Clexane Multidose Vial should not be taken with**

- **Aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots (see section 2).**

**How to use Clexane Multidose Vial**

- **Always use this medicine exactly as your doctor or pharmacist has told you.** Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- **Your doctor or nurse will normally give you Clexane Multidose Vial.** This is because it needs to be given as an injection.

**Storage**

- **Keep this leaflet and the blister pack:**
- **The maximum amount of Clexane Multidose Vial given for the first two injections is 7.500 IU (75 mg).**

**Storing blood clots from forming in the tubes of your dialysis machine**

- **This amount is usually enough for a 4-hour dialysis session.**

**Driving and using machines**

- **Use Clexane Multidose Vial with caution in children.**

**Tests and checks**

- **Your doctor will decide how long you should receive Clexane Multidose Vial.**

**Use in children and adolescents**

- **Use Clexane Multidose Vial with caution in children.**

**Other medicines Clexane Multidose Vial should not be taken with**

- **Aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots (see section 2).**

**How to use Clexane Multidose Vial**

- **Always use this medicine exactly as your doctor or pharmacist has told you.** Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- **Your doctor or nurse will normally give you Clexane Multidose Vial.** This is because it needs to be given as an injection.

**Storage**

- **Keep this leaflet and the blister pack:**
- **The maximum amount of Clexane Multidose Vial given for the first two injections is 7.500 IU (75 mg).**

**Storing blood clots from forming in the tubes of your dialysis machine**

- **This amount is usually enough for a 4-hour dialysis session.**

**Driving and using machines**

- **Use Clexane Multidose Vial with caution in children.**

**Tests and checks**

- **Your doctor will decide how long you should receive Clexane Multidose Vial.**

**Use in children and adolescents**

- **Use Clexane Multidose Vial with caution in children.**

**Other medicines Clexane Multidose Vial should not be taken with**

- **Aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots (see section 2).**

**How to use Clexane Multidose Vial**

- **Always use this medicine exactly as your doctor or pharmacist has told you.** Check with your doctor or pharmacist if you are not sure.

**Having this medicine**

- **Your doctor or nurse will normally give you Clexane Multidose Vial.** This is because it needs to be given as an injection.

**Storage**

- **Keep this leaflet and the blister pack:**
- **The maximum amount of Clexane Multidose Vial given for the first two injections is 7.500 IU (75 mg).**

**Storing blood clots from forming in the tubes of your dialysis machine**

- **This amount is usually enough for a 4-hour dialysis session.**

**Driving and using machines**

- **Use Clexane Multidose Vial with caution in children.**

**Tests and checks**

- **Your doctor will decide how long you should receive Clexane Multidose Vial.**

**Use in children and adolescents**

- **Use Clexane Multidose Vial with caution in children.**

**Other medicines Clexane Multidose Vial should not be taken with**

- **Aspirin (also known as acetylsalicylic acid or ASA), clopidogrel or other medicines used to stop blood clots (see section 2).**

**How to use Clexane Multidose Vial**

- **Always use this medicine exactly as your doctor or pharmacist has told you.** Check with your doctor or pharmacist if you are not sure.
If you are able to give Clexane Multidose Vial to someone else:

- Clexane Multidose Vial should be injected just under the skin on your stomach, but not too near your belly button.
- Do not inject yourself within 5 cm of your belly button (may affect up to 1 in 10 people):
  - hard mass or lump at the injection site.
  - bleeding
  - osteoporosis (a condition where your bones are more likely to break) after long term use
  - an increase in the number of eosinophils in your blood – your doctor will be able to check this by carrying out a blood test
  - pain and bruising at the injection site.
- If you have signs of too much bleeding – such as:
  - bleeding
  - bruising
  - loss of control over your bladder or bowel (so you cannot control when you go to the toilet)
  - swelling
  - severe allergic reaction – the signs may include:
    - rash
    - difficulty breathing or swallowing
    - swelling of the face (particularly in the lower part of your body) when you wake up in the morning
    - large red irregularly shaped skin lesions with or without blisters
    - a feeling of tenderness and swelling in your aching bones
    - yellowing of your skin or eyes and your urine becomes darker in colour – this could be a liver problem.

If you think that you have used too much or too little Clexane Multidose Vial:

- Stop using Clexane Multidose Vial and talk to your doctor or pharmacist immediately.
- Stop taking Clexane Multidose Vial. Start taking vitamin-K antagonists (such as warfarin) to thin your blood – your doctor will be able to check this by carrying out a blood test
- Stop using Clexane Multidose Vial injections until your doctor decides to stop them. If you stop, you could get a blood clot 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 forget to use Clexane Multidose Vial:

- If you forget to give yourself a dose, have it as soon as you remember. Do not take a double dose to make up for a forgotten dose.
- If you stop using Clexane Multidose Vial:
  - uncontrolled high blood pressure on your next visit.

In preparing your injection site:

1) To avoid bruising, do not rub the injection site after you have injected yourself.
2) Drop the used syringe into a sharps container.
3) To avoid infection:
   - Each ml contains 100 mg enoxaparin sodium,

4. Possible side effects

Direct, serious side effects:

- These measures will help protect the treat your doctor straight away:
  - you have any sign of blockage of a blood vessel by a blood clot such as:
    - cramping, pain, redness, warm or swelling in one of your legs – these are symptoms of deep vein thrombosis
    - breathlessness, chest pain, fainting or coughing up blood – these symptoms are of a pulmonary embolus
  - you have a painful rash of red spots under the skin which do not go away when you put pressure on them.
  - you should tell your doctor straight away:
    - if you have signs of too much bleeding – such as:
      - bleeding
      - bruising
      - loss of control over your bladder or bowel (so you cannot control when you go to the toilet)

Reporting of side effects

- If you get any side effects, talk to your doctor or pharmacist immediately. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clexane Multidose Vial

- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of the month.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice a breach of the pack. Do not throw any unneeded or unwanted medicines into household waste or the toilet.
- Marketing Authorisation Holder
  - Not all pack sizes may be marketed.

Clexane Multidose Vial looks like and contains:

- The active substance is enoxaparin sodium
- Each ml contains 100 mg enoxaparin sodium, equivalent to 10 000 IU of anti-Xa activity
- Each multi-dose vial of 3 mL contains 30 000 IU of anti-Xa activity
- The other ingredients are benzyl alcohol and water for injections.