

Package leaflet: Information for the user
tinzaparin sodium 10,000 IU/ml

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet tinzaparin sodium 10,000 IU/ml will be called tinzaparin.

What is in this leaflet

1. What tinzaparin is and what it is used for
2. What you need to know before you use tinzaparin
3. How to use tinzaparin
4. Possible side effects
5. How to store tinzaparin
6. Contents of the pack and other information

1. What tinzaparin is and what it is used for

Tinzaparin is a type of heparin – a low molecular weight heparin – and belongs to a group of medicines called anticoagulants; these medicines affect how your blood clots.

Tinzaparin prevents clotting, allowing normal blood flow through the arteries and veins.

Tinzaparin is used to:

- Prevent blood clots in adults before and after an operation.
- Prevent blood clots in adults who have an increased risk of blood clots e.g. due to an acute illness with limited mobility.
- Prevent blood clots being formed in haemodialysis equipment in patients undergoing haemodialysis or haemofiltration. In haemodialysis, wastes and fluids from the blood are removed by a dialysis machine and a dialysis filter, which acts as a kind of artificial kidney.

2. What you need to know before you use tinzaparin

Do not use tinzaparin

- If you are allergic to tinzaparin or any of the other ingredients of this medicine (listed in section 6).
- If you have ever had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) - this reaction is called heparin-induced thrombocytopenia (HIT).
- If you have ever had a major bleed (for instance: in the brain, spine, eye or stomach, into a muscle or the womb, or any conditions which make you bleed severely, such as haemophilia).
- If you have a condition called septic endocarditis (an inflammation of the lining of the heart and heart valves).

Do not give this medicine to a premature baby, a newborn baby or a baby up to 1 month old as it contains benzyl alcohol (see “Important information about some of the ingredients of tinzaparin” below).

The use of tinzaparin vials should be avoided if you are pregnant or think you may be pregnant due to the presence of benzyl alcohol (see “Pregnancy and breast-feeding”).

Do not give this medicine to patients who are using tinzaparin to treat blood clots and are going to receive spinal/epidural anaesthesia or lumbar puncture.

Warnings and precautions

Important: If you are having an epidural/spinal anaesthetic

Your doctor will decide if you can have an epidural/spinal anaesthetic if you are using tinzaparin. You must wait 12 hours after your last injection of tinzaparin before having a lumbar puncture or epidural/spinal anaesthetic placed.

You must wait at least 4 hours after having a spinal anaesthetic, or after the catheter has been removed, before you start using tinzaparin again.

If you have an anaesthetic your doctor or nurse will make regular checks. This is to check if you are getting any major bleeding or bruising around your spine. This may cause paralysis that could be permanent. Any signs this may be happening to you include tingling, weakness or numbness in your lower legs or body, back pain or problems in going to the toilet. This happens very rarely.

You may have a blood test before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood. Do not inject tinzaparin into a muscle. See section 3, "How to use tinzaparin".

This medicine may make you bleed more easily, so when you are being given other injections or having any procedures carried out, tell the doctor, nurse or dentist that you are using tinzaparin.

Talk to your doctor, pharmacist or nurse before using tinzaparin

- If you are pregnant, or think you may be pregnant. See the section "Pregnancy and breast-feeding".
- If you have a condition which makes you more likely to bleed.
- If you are being treated with any other injections into your muscles.

- If you have any medical condition such as diabetes mellitus or metabolic acidosis which may cause high levels of potassium in your blood (hyperkalaemia).
- If you have an artificial heart valve.
- If you have kidney problems.

Tinzaparin should not be interchanged with other low molecular weight heparin products. This is because they are not exactly the same and you could experience problems with your blood clotting.

Elderly people

Because kidney problems are more likely if you are elderly, you may have a blood test to check how well your kidneys are working and to monitor the activity of tinzaparin.

Children and adolescents

Tinzaparin is not intended for use in children and adolescents under the age of 18 years.

Other medicines and tinzaparin

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes any medicines bought without a prescription.

You must tell your doctor, pharmacist or nurse if you are taking any of the following medicines as you may be likely to bleed more easily:

- Non-steroidal anti-inflammatory drugs (such as ibuprofen or diclofenac): for arthritis or aches or pains.
- Aspirin: either for reducing pain and inflammation, or the lower dose for thinning of the blood.
- Platelet aggregation inhibitors (such as clopidogrel): for stopping harmful blood clots forming.
- Thrombolytic agents (such as streptokinase): for dissolving blood clots.

- Vitamin K antagonists (such as warfarin): for stopping harmful blood clots.
- Activated protein C: for getting rid of blood clots.
- Anticoagulation, taken by mouth (such as rivaroxaban, dabigatran or apixaban): for stopping harmful blood clots.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or midwife for advice before using this medicine.

The use of tinzaparin vials should be avoided if you are pregnant or think you are pregnant due to the presence of benzyl alcohol (see below for further details). Your doctor will prescribe a different formulation of tinzaparin.

Special precautions are required if you will have an epidural anaesthetic to help you with your labour when you are using tinzaparin. (See ‘Warnings and precautions’.)

Driving and using machines

This medicine should not have any effect on your ability to drive or use machines. However, you should check with your doctor if you feel any side effect that may stop you from driving or using machines.

Important information about some of the ingredients of tinzaparin

Tinzaparin sodium 10,000 IU/ml vial contains benzyl alcohol and sodium:

- This medicine contains 10 mg benzyl alcohol in each mL.
- Benzyl alcohol may cause allergic reactions.
- Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children. Do not use for more than one week in young children (less than 3 years old), unless advised by your doctor or pharmacist.
- Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).
- Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).
- This medicine contains less than 23 milligrams (mg) sodium per mL and is therefore essentially “sodium free”.

Please ask your doctor or pharmacist if you are worried about any of the ingredients in this medicine.

3. How to use tinzaparin

Tinzaparin will be given to you by your doctor or your nurse. Tinzaparin should not be mixed with any other injection.

How much tinzaparin to use

Adults, including the elderly:

To prevent blood clots forming in your veins

Your doctor or nurse will inject tinzaparin under the skin (subcutaneous injection). The dose and the length of your treatment will depend on the type of operation or illness you are having. Your doctor will prescribe the right dose for you and tell you how long your treatment with tinzaparin will last.

To prevent blood clots forming in connection with haemodialysis or haemofiltration

Tinzaparin will be given either into the tubes of the haemodialysis machine or into your vein. The dose will depend on the duration of dialysis.

Use in children and adolescents

There is limited experience of use in children and adolescents. Tinzaparin is not intended for use in children and adolescents under the age of 18 years.

If you use more tinzaparin than you should

If you feel unwell or think you may have been given too much, tell your doctor or nurse straight away because you may start to haemorrhage (bleed severely) and need to be given another injection of a medicine called protamine sulfate to stop you bleeding.

If you forget to use tinzaparin

If you think that you have missed a dose, it is important that you talk to your doctor or nurse as soon as you remember and get advice on what to do.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects most often reported are blood problems and skin reactions, especially where your injection has been given.

Important side effects to look out for:

You must get urgent medical help if you have any of the following symptoms. You may be having serious allergic reactions. These are rare (may affect up to 1 in 1000 people).

- You have difficulty breathing.
- Your face or throat swell.
- Your skin develops a severe rash.
- You experience blistering of the skin, mouth, eyes or genitals or your skin peels.
- Blood spots near the injection site which could develop into a purple blister surrounded by red inflamed skin.

You must get urgent medical help if you have any of the following symptoms after having an epidural or spinal anaesthetic. You may be developing paralysis:

- Tingling, weakness or numbness in your legs or lower body.
- Back pain.
- Problems in going to the toilet.

You should tell your doctor straight away if you spot any of the following signs which mean you may be starting to bleed severely:

- Red or brown urine.
- Black tarry stools.
- Unusual bruising.
- Bleeding from your nose, or mouth or any operation wound that will not stop.

Common side effects (may affect up to 1 in 10 people)

- Bleeding (haemorrhage).
- Anaemia. Reduction in red blood cells which can make the skin pale and cause weakness and breathlessness.
- A pooling of blood in tissues which may result in the skin appearing dark in colour, similar to a large bruise.
- Pain, itching, bruising or bleeding, redness, swelling, nodules or hard lumps under your skin where the injection was given.

Uncommon side effects (may affect up to 1 in 100 people)

- Changes in your blood test results. There may be a change in the clotting cells (platelets) in your blood. These tests will return to normal after tinzaparin is stopped.
- An allergic reaction. You may be sensitive to one of the ingredients in this medicine.
- Bruising, red or purple spots under your skin.
- Some blood tests may also show a change in the way your liver is working. These tests will return to normal when tinzaparin is stopped.
- An itchy red rash with heat and swelling on your skin (dermatitis).
- Rash.
- Itchy skin.

Rare side effects (may affect up to 1 in 1000 people)

- Your blood may form more harmful clots. A drop in the number of clotting cells (platelets) in your blood may give you these symptoms. Your doctor can explain this more.
- Changes in your blood test results. The amount of potassium may be increased. This is more likely to happen if you have severe kidney problems or diabetes. Your doctor can explain this more.
- Hives.
- Your bones may weaken and break more easily. This is known as osteoporosis and has been seen in patients using heparin for a long time.
- Prolonged, painful erections in men.

Paediatric population

Limited information derived from one study and postmarketing data indicates that the pattern of adverse reactions in children and adolescents is comparable to that in adults.

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 also report side effects directly via the Yellow Card Scheme at: www.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 tinzaparin

- 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 carton and label (EXP). The expiry date is the last day of that month.
- Chemical and physical in use stability has been demonstrated for 28 days at 30°C. From a microbiological point of view, once opened, the product may be stored for a maximum of 28 days at 30°C.
- This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What tinzaparin contains**

- The active substance is tinzaparin sodium.
- Each vial contains 20,000 IU of tinzaparin sodium in 2 millilitres (ml) of solution.
- The other ingredients are benzyl alcohol, sodium acetate trihydrate, sodium hydroxide, hydrochloric acid, concentrated and water for injections.

You can find important information about some of the ingredients near the end of section 2, just before section 3.

What tinzaparin looks like and contents of the pack

Tinzaparin is a straw coloured liquid.

Tinzaparin comes in a glass vial containing 2 ml.

There are 1, 2, 5 or 10 vials in a carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: LEO Laboratories Limited, Maidenhead, Berkshire SL6 3UD, UK.

Manufacturer: Vianex S.A. – Plant A, 12 Km National Road Athens Lamia, Metamorfossi, 144 51,
Greece

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For information in large print, Braille or audio/CD, telephone +44 (0)1844 347333.