

Package leaflet: Information for the user
innohep® 10,000 IU/ml
solution for injection
tinzaparin sodium

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 innohep 10,000 IU/ml will be called innohep.

What is in this leaflet

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

1. What innohep® is and what it is used for

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

innohep 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 innohep®

Do not use innohep

- If you are allergic (hypersensitive) to tinzaparin or any of the other ingredients of this medicine (listed in section 6).
- If you know that you have, or have ever had, a big drop in the clotting cells (platelets) in your blood caused by having any type of heparin (reaction called heparin-induced thrombocytopenia).
- If you have any condition which makes you bleed severely, such as haemophilia or are currently bleeding from any part of your body.
- If you know that you have a condition called 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.

If you are pregnant, please also read the section of this leaflet 'Pregnancy, breast-feeding and fertility'.

Warnings and precautions

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

You must wait at least 4 to 6 hours after having a spinal anaesthetic, or after the catheter has been removed, before you start using innohep again.

Talk to your doctor, pharmacist or nurse before using innohep:

- If you have any condition which makes you more likely to bleed easily. Ask your doctor if you are unsure.
- This medicine must not be injected into your muscles. You should not receive any other injections into your muscles while using innohep as you may bruise.
- Your doctor may take a blood test before you start having this medicine, and while you are having it. This is to check the level of the clotting cells (platelets) and potassium in your blood.
- If you know that you have any medical condition (e.g. diabetes) which may cause high levels of potassium in your blood (hyperkalaemia). Ask your doctor if you are unsure.
- If you have an artificial heart valve.
- If you have kidney problems. This is more likely if you are elderly. Your doctor may need to adjust your dose or do extra tests.

Children and adolescents

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

Other medicines and innohep

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

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: for reducing pain and inflammation, or for thinning 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: A protein which may be given to you to control blood clotting and inflammation.
- Oral anticoagulants: Any tablet which may be given to stop harmful blood clots.

Pregnancy, breast-feeding and fertility

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

Tell your doctor if you become pregnant while having this medicine.

The use of innohep 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 innohep.

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

Driving and using machines

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

innohep 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 1 mmol sodium (23 milligrams) per mL, that is to say essentially "sodium free".

3. How to use innohep®

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

How much innohep to use

Adults, including the elderly:

To prevent blood clots forming in your veins

Your doctor or nurse will inject innohep 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 innohep will last.

To prevent blood clots forming in connection with haemodialysis or haemofiltration

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

If you use more innohep than you should

You may start to haemorrhage (bleed severely) and need to be given another injection of a medicine called protamine sulfate to stop you bleeding. Please read section 4 so you can spot any signs that this may be happening to you.

If you forget to use innohep

If you think that you may have missed a dose, then tell your doctor, pharmacist or nurse.

If you stop using innohep

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 (e.g. bleeding or changes in blood tests) and skin reactions near where the injection was 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 should tell your doctor straight away if you spot any of the following signs which mean you may be starting to bleed severely. This is uncommon (may affect up to 1 in 100 people).

- Red or brown urine.
- Black tarry stools (bowel movements).
- Unusual bruising (very painful, large or dark bruises).
- Bleeding from your nose or mouth or any wound that will not stop.

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.

Common (may affect up to 1 in 10 people)

- Reduction in red blood cells which may make the skin pale and cause weakness or breathlessness.
- Less serious bleeding from a wound, blood in your urine or bowel movements.

- A pooling of blood in tissues which may result in the skin appearing dark in colour, similar to a large bruise.
- Pain, itch, bruising or bleeding, redness, swelling, nodules or hard lumps under your skin where the injection was given.

Uncommon (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 when innohep is stopped.
- An allergic reaction. You may be sensitive to one of the ingredients of this medicine.
- Bruising, red or purple blood 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 innohep is stopped.
- An itchy red rash with heat and swelling on your skin (dermatitis).
- Rash.
- Itching.

Rare (may affect up to 1 in 1000 people)

- Your blood may form more harmful clots. A big drop in clotting cells (platelets) in your blood may give you these symptoms. You will need to stop using this medicine. Your doctor can explain this more.
- An increase in clotting cells (platelets).
- 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.
- Swelling of the face or throat.
- Hives.
- A decrease in bone density (osteoporosis) could occur if you are treated for a long time. Your bones may get weak and break more easily.
- 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store innohep®

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the carton and label (EXP). The expiry date refers to 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 use this medicine if you notice any cloudiness or particles in the liquid.

- The liquid may turn yellow over time but this does not affect the product quality.

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

6. Contents of the pack and other information

What innohep contains

- The active ingredient is tinzaparin sodium. Each 1 millilitre (ml) contains 10,000 IU of 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 of this leaflet.

What innohep looks like and contents of the pack

innohep solution for injection is a clear to straw coloured liquid.

innohep solution for injection comes in a glass vial containing 2 ml.

There are ten vials in a carton.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

LEO Laboratories Limited, Cashel Road,
Dublin 12

Manufacturer:

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

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