

PACKAGE LEAFLET: INFORMATION FOR THE USER

innohep® 10,000 IU in 0.5 ml

innohep® 14,000 IU in 0.7 ml

innohep® 18,000 IU in 0.9 ml

solution for injection (20,000 IU/ml)

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 the innohep® syringe 20,000 IU/ml presentations listed above 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® belongs to a group of medicines called low molecular weight heparins which help to stop the blood from clotting.

innohep® is used in adults to treat:

- Harmful blood clots that have formed in a vein deep inside your body. This is usually in your leg (deep vein thrombosis or DVT for short).
- Harmful blood clots that have formed may travel in your bloodstream and then get stuck in another blood vessel (thromboembolism). A clot may block the blood supply to your lungs (pulmonary embolism or PE for short). It can cause breathing difficulties.
- Blood clots that have developed because of cancer and to prevent further clots from forming.

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 in your medicine. You can find a list of these ingredients in section 6 of this leaflet.
- 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).
- **Important:** You must not have an epidural/spinal anaesthetic within 24 hours after your last dose of innohep®. 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.

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

! Warnings and Precautions

Talk to your doctor or pharmacist 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.
- If you have asthma as this product contains sodium metabisulfite.

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 or pharmacist 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 or pharmacist 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. You may be likely to bleed more easily.
- 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 and Breast-feeding

Please ask your doctor or pharmacist for advice before using innohep®:

- If you are pregnant, or think you are pregnant.
- If you are breast-feeding.

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

You must not have an epidural anaesthetic to help you with labour or for surgery within 24 hours of your last dose of innohep®.

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

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:

- Sodium metabisulfite. This is a preservative. It may rarely cause severe hypersensitivity reactions and bronchospasm. Please read section 4 so you can spot any signs that this may be happening to you.
- Sodium. This medicinal product contains less than 1 mmol sodium (23 milligrams) per dose, i.e. essentially "sodium free".

3. How to use innohep®

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. innohep® is usually given to you by a doctor or nurse at least to start with, by injection under the skin. innohep® should not be mixed with any other injection.

Your doctor may decide that you or a carer may inject this medicine.

Your doctor or nurse will show you how to inject yourself with the syringe.

How much innohep® to inject

Your doctor will prescribe the right dose for you.

Adults, including the elderly:

The dose depends on your weight (called bodyweight). The treatment will be once daily for at least 6 days and may be continued for up to 6 months. The need for continued treatment beyond 6 months will be evaluated by your doctor. Your doctor will tell you how long your treatment with innohep® will last.

Use in children and adolescents:

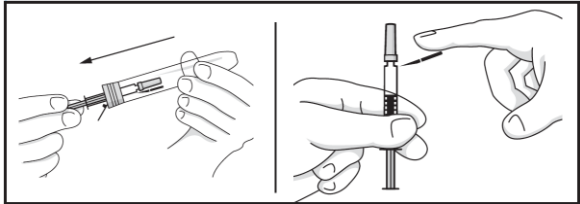
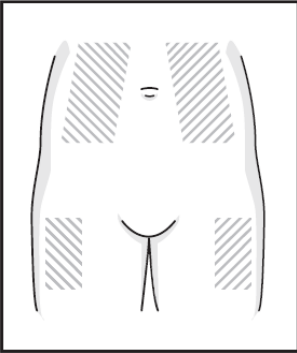
There is limited experience of use in children and adolescents. innohep® is not intended for use in children and adolescents under the age of 18 years.

How to inject yourself with innohep®

Usually your doctor or nurse will give you instructions on how to use innohep® before you give yourself the first injection. Your doctor or nurse will tell you the volume to inject. Remember you may not need to inject the entire contents of the syringe. You should inject yourself at the SAME TIME every day. Make sure you contact your doctor if you are unsure about how to inject yourself or if you have any questions about innohep®.

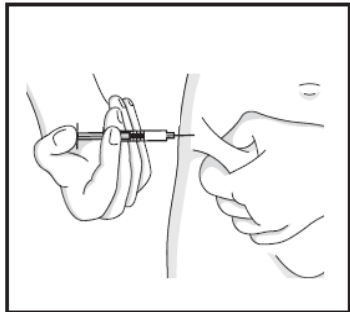
When giving yourself an injection, make sure you:

1. Thoroughly wash your hands with soap and water. Dry your hands.
2. Sit or lie in a position so that you can see the skin where you are going to inject yourself (usually the abdomen). This can comfortably be done in a lounge chair, recliner or bed propped up with pillows.
3. Decide where to inject yourself. This is usually on the right or left side of the abdomen (stomach). You must not inject yourself within 5 cm (2 inches) of your belly button. You may also inject into the sides of your thigh, lower back, upper leg or upper arm. Do not inject near any scars or bruises. Each time you inject yourself, choose the opposite side from the site of your previous injection.
4. Clean the area of the skin, as you have been told to do by your doctor or nurse, and allow to dry before you inject yourself.



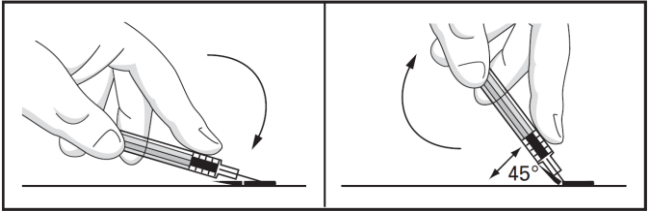
5. Carefully take the syringe out of its plastic container by bending the cap all the way back and sliding the syringe out. Bend the orange safety device down away from the cap on the needle. Remove the protective needle cap without bending the needle. To keep the needle clean, make sure it does not touch anything. The syringe is now ready for use.

IMPORTANT. If your dose is less than that in the syringe, hold the syringe vertically with the needle pointing upwards and gently remove the excess by pressing the plunger into the syringe. There is no need to remove the air bubble if you need the total quantity in the syringe for your dose.



6. Hold the syringe in your writing-hand like you would hold a pen. With your other hand, make a fold of your skin by gently pinching the area where you are going to inject yourself with your thumb and forefinger.
7. With the syringe at a right angle to your body (pointing straight, not at an angle), insert the needle fully into the skin fold.

8. Continue to hold the skin fold, press down on the plunger slowly over 10–15 seconds. This delivers the medication into the fatty tissue.
9. Pull the needle completely out of the skin and then let go of the skin fold. Do not rub or massage the place where you injected yourself – this can lead to bruising.



10. Using a hard surface, bend the orange safety device so it is now pointing in the same direction as the needle (back to its original position). Then with the safety device flat against a hard surface such as a table, gently push downwards until the needle clicks in to the device. Then continue to push downwards against the hard surface, so that the needle and device are at a 45 degree angle to the syringe.
11. The used syringe, even when the orange safety device is in place, should be handled with care. The used syringe should be disposed of in a “sharps” container (i.e. a special bin for needles) immediately. If a “sharps” container is not readily available then please put the used syringe back into the plastic container and close the lid by pressing down on the lid until it clicks into the slot provided. Dispose of the syringe carefully, as instructed by your healthcare professional. **Never put syringes or needles in the household rubbish.**

For the attention of the healthcare professional:

Please dispose of the used syringe in accordance with your institution/employer’s standard procedures for disposal of used syringes.

How to dispose of syringes safely

The used syringe should be disposed of in a “sharps” container (i.e. a special bin for needles). If a “sharps” container is not available then please put the used syringe (needle first) back into the plastic container and close the lid by pressing down on the lid until it clicks in to the slot provided. This prevents accidental injury. Never throw syringes into the household waste.

If you use more innohep® than you should

If you think you may have injected yourself with too much innohep® tell your doctor or nurse straight away.

You may start to haemorrhage (bleed). 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 forget to inject yourself, or if you think that you may have missed a dose, then tell your doctor or nurse. If you have any further questions about taking this medicine, please ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, innohep® 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 a serious allergic reaction. This is rare (may affect less than 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 less than 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.

- 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 post marketing 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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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 innohep® if you notice any cloudiness or particles in the liquid.
- Do not use this medicine after the expiry date stated on the label (EXP). The expiry date refers to the last day of that month.
 - The liquid may turn yellow over time but this does not affect the product quality.
- Do not store above 25° C.
- Each syringe is intended to be used only once.

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 substance is tinzaparin sodium. innohep® 20,000 IU/ml syringes contain 20,000 IU of tinzaparin sodium in each millilitre (ml).
- The other ingredients are sodium metabisulfite, sodium hydroxide 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® comes in a syringe containing
0.5 ml (10,000 anti-Factor Xa IU),
0.7 ml (14,000 anti-Factor Xa IU),
0.9 ml (18,000 anti-Factor Xa IU).

There are 2 or 10 syringes in a carton. Not all presentations and pack sizes may be marketed.

Manufacturer

Laboratoires LEO, S.A, France

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Parallel Product Authorisation Number:

innohep® 10,000 IU in 0.5 ml PPA 465/322/1
innohep® 14,000 IU in 0.7 ml PPA 465/322/3
innohep® 18,000 IU in 0.9 ml PPA 465/322/4

innohep® is a registered trademark of LEO Pharma A/S.

For further information about this product contact the local representative of the marketing authorisation holder:

Medical Division, LEO Laboratories Ltd, Dublin 12, Ireland,
Telephone: +353 1 490 8924, Email: medical-info.ie@leo-pharma.com

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