

Package Leaflet: Information for the user

Heparin (Mucous) Injection BP 1,000 and 5,000 Units/ml

heparin sodium

Read all of this leaflet carefully before you start having 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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet Heparin (Mucous) Injection BP will be called heparin.

What is in this leaflet

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

1. What heparin is and what it is used for

Heparin contains the active substance known as heparin sodium. Heparin belongs to a group of medicines called anticoagulants.

These medicines affect how the blood clots. Heparin prevents clotting, allowing normal blood flow through the arteries and veins.

Heparin is used to help:

- stop harmful blood clots in your veins growing bigger (treatment).
- stop harmful blood clots forming in your veins (prevention).
- stop harmful blood clots forming in the tubing of an artificial kidney machine during kidney dialysis (haemodialysis).

An example is a harmful blood clot that has been formed in a deep vein (deep vein thrombosis, DVT). This usually happens in a leg. Another example is a clot that has travelled to the lung and caused a blockage (pulmonary embolism, PE). This can cause breathing difficulties and chest pain.

It is more likely these clots will form if you are either overweight, pregnant, have certain blood disorders or have already had a PE, DVT, heart attack or stroke. They may also happen if you do not move around for long periods of time. This could be because you have had surgery or you have another illness.

2. What you need to know before you have heparin

Do not have heparin

- If you are allergic (hypersensitive) to heparin sodium or any of the other ingredients in 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); a reaction called heparin-induced thrombocytopenia.
- If you have a major bleed (for instance in the brain, spine, eye, stomach, into a muscle or womb) or any condition which makes you bleed severely, such as haemophilia.
- If you have very high blood pressure.
- If you have severe liver problems.
- If you have a stomach ulcer.
- If you have a condition called septic endocarditis (an inflammation of the lining of the heart and heart valves).
- If you have had a brain haemorrhage (bleeding inside your brain).
- If you have an injury to your spine, head, eyes or ears.
- If you have recently had, or are about to have an operation involving your spine, head, eyes or ears.
- If you may be having a miscarriage.

Important: If you are having an epidural or spinal anaesthetic

You must remind your doctor that you are having heparin before you receive any anaesthetic.

After you have the 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.

After you have the anaesthetic, your doctor will tell you when you can have your medicine again.

This medicine should not be given 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 and breast-feeding”.

Warnings and precautions

This medicine must not be injected into your muscles. You should not receive any other injections into your muscles while having heparin as this may lead to bruising.

Talk to your doctor or nurse before having heparin:

- If you have any condition which makes you more likely to bleed more easily. Ask your doctor if you are unsure.
- If you are allergic (hypersensitive) to low molecular weight heparins, such as tinzaparin, enoxaparin or dalteparin.
- If you are taking any medication that affects your blood clotting process.
- If you have kidney problems.
- If you have liver problems.
- If you have problems with your blood pressure (hypertension).
- If you have a medical condition (e.g. diabetes, kidney failure or metabolic acidosis) which may cause high levels of potassium in your blood (hyperkalaemia). Ask your doctor if you are unsure.
- If you know you are sensitive to methyl or propyl parahydroxybenzoate which are ingredients in this medicine. Ask your doctor or nurse for advice as these may cause allergic reactions and may also very rarely lead to breathing difficulties.
- If you are on a controlled sodium diet. Ask your doctor or nurse for more advice.

Your doctor may take a blood test before you start having this medicine, and at intervals while you are having it. This is so the doctor can check you are receiving the right dose. This is also to check the level of the clotting cells (platelets) and potassium in your blood.

Children

- This medicine contains benzyl alcohol. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gaspingsyndrome”) 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..

Other medicines and heparin

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

You must tell your doctor or nurse if you are taking any of the following medicines as they are likely to affect your blood clotting process and make you bleed more easily:

- ACE inhibitors or angiotensin II antagonists, such as enalapril, losartan or valsartan: for treating high blood pressure or heart problems. You may get too much potassium in your blood.
- Aspirin either for reducing pain and inflammation for thinning of the blood.
- Non-steroidal anti-inflammatory drugs such as ibuprofen or diclofenac: for arthritis or aches or pains.
- Selective serotonin reuptake inhibitors (SSRIs) such as citalopram, fluoxetine or sertraline: anti-depressants used in the treatment of depression, anxiety and some personality disorders.
- 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.
- Glyceryl trinitrate infusion: for treating angina. This may reduce the effect of heparin.
- Dextrans: for increasing your blood volume.
- Anticoagulants taken by mouth such as rivaroxaban, dabigatran or apixaban, which may be given to stop harmful blood clots.

Your doctor may carry out check-ups on you, including blood tests, if you take or use any of these medicines at the same time as heparin.

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, nurse or midwife for advice before having this medicine.

If you become pregnant while having this medicine, tell your doctor.

Special precautions are required if you will have an epidural anaesthetic to help with your labour when you are having heparin (see section 2).

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 heparin

Heparin contains

- Benzyl alcohol. This may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gaspingsyndrome”) 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”).

- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). These are preservatives. These may cause allergic reactions (possibly delayed) and may also rarely cause breathing difficulties. This may happen at any time after you have your medicine. Please read section 4 so you can spot any signs this may be happening to you.
- Heparin (Mucous) Injection BP – 1,000 IU/ml - Sodium. This medicinal product contains less than 1 mmol sodium (23 mg) per 5,000 International Units (IU) dose, i.e. essentially ‘sodium-free’.
- Heparin (Mucous) Injection BP – 5,000 IU/ml - Sodium. This medicinal product contains less than 1 mmol sodium (23 mg) per 25,000 International Units (IU) dose, i.e. essentially ‘sodium-free’.

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

3. How to use heparin

This medicine will be given to you by a doctor or nurse. Your doctor will prescribe the right dose of heparin for you.

Heparin should not be mixed with any other injection. It may be given subcutaneously (under your skin) or intravenously (into your vein).

If you have more heparin than you should

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

If you have missed a dose of heparin

Your doctor or nurse will give you this medicine. If you think that you have missed a dose then tell your doctor or nurse.

If you have any further questions about using this medicine, please ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side effects to look out for

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.**

Although severe bleeding is uncommon, permanent disability and fatality has been reported in some cases.

You must get urgent medical help if you have any of the following symptoms. You may be having a serious allergic reaction:

- **You have difficulty breathing**
- **Your face or throat swell**
- **Your skin develops a severe rash**

- **Your skin develops blisters at the site of your injection.**

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.**

Other possible side effects

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

- Bleeding (haemorrhage). This may be more likely if you are having a high dose of heparin.
- Appearance of a large bruise like spot. This is caused due to a localised collection of blood clot on skin or eye area.
- Dark coloured urine.
- Reddening of the skin.
- Changes in your blood test results caused due to increase in body enzymes. Your doctor can explain this more.

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

- Changes in your blood test results. There may be a drop in the platelet count (clotting cells) in your blood. This may increase the risk of bleeding and bruising. There may also be an increase in time it takes for your blood cells to clot. Ask your doctor or nurse for more advice.
- Allergic reactions.
- Increase in the amount of potassium in your blood.
- Rash.
- Itching.
- Itchy and swollen rash (hives).
- Blood spots near the injection site which could develop in to a purple blister surrounded by red inflamed skin.
- Osteoporosis. Your bones become less strong and can break more easily. This has been seen in patients taking heparin for a long time.
- Prolonged and painful erection in men.
- Local injection site allergic reactions such as swelling, redness and/or pain may occur.

Reporting of side effects

If you get any side effects, talk to your doctor 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 heparin

- Keep this medicine out of the sight and reach of children.
- Do not use the medicine after the expiry date on the vial. The expiry date refers to the last day of that month.
- Shelf-life: 3 years
- This medicinal product does not require any special storage conditions.
- Chemical and physical in-use stability has been demonstrated for 28 days at 30°C. Once opened, from a microbiological point of view, the product may be stored for a maximum of 28 days at 30°C. Other in-use storage times and conditions are the responsibility of the user.

Do not throw away any medicines via waste water 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 heparin contains

- The active substance is heparin sodium.
- There are two strengths of this product containing either 1,000 or 5,000 IU of heparin sodium in each millilitre (ml).
- The other ingredients are benzyl alcohol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium citrate, sodium chloride, hydrochloric acid (for pH adjustment) 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 heparin looks like and contents of the pack

Heparin is a clear, colourless to yellowish liquid.

This medicine comes in glass vials containing 5 ml.

There are 5, 10 or 50 vials of heparin 1,000 and 5,000 IU/ml in a carton*.

Not all pack sizes may be marketed.

Marketing Authorisation Holder/Manufacturer

Marketing Authorisation Holder:

LEO Laboratories Limited, Honey Lane, Hurley, Maidenhead, Berkshire SL6 6RJ, UK.

Manufacturer: LEO Pharma A/S, DK 2750, Ballerup, Denmark.

This leaflet was last revised in October 2020.

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

* When printed, only the marketed packs will be mentioned.