

## **Package leaflet: Information for the user**

### **Heparin sodium 1,000 and 5,000 IU/mL solution for injection or concentrate for solution for infusion**

**Read all of this leaflet carefully before you start taking 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.

#### **What is in this leaflet**

1. What heparin is and what it is used for
2. What you need to know before you use 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 belongs to a group of medicines called anticoagulants.

Heparin changes the way your blood clots. This means your blood keeps flowing smoothly inside your blood vessels. These are the tubes that carry blood around your body and are called arteries and veins.

Heparin is therefore used to treat:

- blood clots in leg veins (deep vein thrombosis)
- blood clots in the lung (pulmonary embolism) as well as for:
  - the treatment of chest pains resulting from disease of the heart arteries (unstable angina pectoris)
  - the treatment of severe blockages affecting arteries in the legs (acute peripheral arterial occlusion)

It is also used during heart and lung operations and during kidney dialysis.

#### **2.What you need to know before you use Heparin**

##### **Heparin Infusion should not be given to you:**

- If you are allergic (hypersensitive) to heparin or any of the other ingredients of this 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 (thrombocytopenia).
- If you are currently bleeding from anywhere in the body, (apart from your normal period which does not stop you being given heparin injection).
- If you had a major trauma.
- If you have any condition which makes you bleed severely, such as haemophilia.
- If you bruise easily (fragile capillaries) or have lots of purple spots that look like bruises (purpura).
- If you have very high blood pressure.
- If you have severe liver problems, which can lead to bleeding into the oesophagus (gullet).
- 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, brain, eyes or ears, a lumbar puncture or local anaesthetic nerve block, or some other procedure where bleeding could be a

problem.

- If you are about to be treated for pain and inflammation with intravenous diclofenac.
- If you may be having a miscarriage.
- If you are suffering from tuberculosis.
- If you drink large amounts of alcohol.
- If you have had severe skin problems resulting from previous heparin treatment.

**Important: If you are having an epidural or spinal anaesthetic**

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

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

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 take your medicine again.

**Warnings and precautions**

Talk to your doctor before heparin infusion is given to you:

- If you have any condition which makes you more likely to bleed more easily (for example a stomach ulcer, hiatus hernia, inflammation of the heart, problems in the back of your eye, haemorrhoids (piles), cancer). Ask your doctor if you are unsure.
- If you have previously had an allergic reaction to low molecular weight (LMW) heparins, such as tinzaparin, enoxaparin or dalteparin. A small test dose of heparin sodium infusion may be given first.
- If you have kidney or liver diseases. Your doctor may decide that a lower dose is necessary.
- If you have high blood pressure (hypertension).
- If you have diabetes mellitus.
- If you know you have a condition called metabolic acidosis.
- If you have high levels of potassium in your blood or are taking medicine that may increase the potassium level in your blood (e.g. amiloride, triamterene, eplerenone or spironolactone). If any of these apply you may need to have a blood test before the start of your heparin treatment. If you are unsure, ask your doctor or nurse.
- If you are taking another medicine that may affect your blood clotting. For a list of these medicines see the section “other medicines and heparin”.

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

This medicine may make you bleed more easily. The doctor or nurse should take care when giving you any other injections or procedures.

**Other medicines and heparin**

Please tell your doctor or nurse if you are taking, or have recently taken 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:

- ACE inhibitors (e.g. captopril, enalapril, lisinopril, ramipril), angiotensin II antagonists (e.g. losartan or valsartan) or a renin inhibitor drug called aliskiren, used for treating high blood

pressure or heart problems.

- You may get too much potassium in your blood.
- Non-steroidal anti-inflammatory drugs, such as ibuprofen, diclofenac or Ketorolac, for arthritis or aches or pains. You may be likely to bleed more easily.
- Salicylates, such as aspirin: for reducing pain and inflammation, or for stopping harmful blood clots forming. You may be likely to bleed more easily.
- Platelet aggregation inhibitors, such as clopidogrel, dipyridamole, epoprostenol or ticlopidine: for stopping harmful blood clots forming. You may be likely to bleed more easily.
- Thrombolytic agents, such as streptokinase: for dissolving blood clots. You may be likely to bleed more easily.
- Vitamin K antagonists, such as warfarin: for stopping harmful blood clots. You may be likely to bleed more easily.
- Glyceryl trinitrate infusion: for treating angina. This may reduce the effect of heparin.
- Dextrans: for increasing your blood volume, used to treat shock. You may be likely to bleed more easily.
- Probenecid, used in the treatment of gout.
- Cephalosporins (cefaclor, cefixime and ceftriaxone), used to treat infections. You may be likely to bleed more easily.
- Medicines that may increase the potassium level in your blood (e.g. amiloride, triamterene, eplerenone or spironolactone).

If you need one of the above medicines your doctor may decide to alter the dose of heparin infusion or the other medication.

Tobacco smoke can also interfere with the working of heparin. You should inform your doctor if you smoke.

The presence of heparin in the blood can affect the results of some blood tests such as thyroid tests and the levels of calcium or some antibiotics (e.g. gentamicin) in the blood.

### **Pregnancy and breast-feeding**

If you are pregnant or might be pregnant, wish to become pregnant or have a history of, or known risk to miscarriage, tell your doctor before you are given Heparin infusion.

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

If you are being given heparin, bleeding may be a problem during pregnancy or after delivery. Your bones may get thinner if you receive heparin for a long time during pregnancy.

If you are pregnant and are going to have an epidural anaesthetic, you should stop having your medicine. Ask your doctor for advice.

If you are breast-feeding, ask your doctor for advice before having Heparin infusion.

### **Driving and using machines**

Heparin infusion has not been reported to affect ability to drive or operate machines.

### **Important information about some of the ingredients of Heparin infusion**

This medicine contains:

Heparin sodium 1,000 IU/mL solution for injection or concentrate for solution for infusion

This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

Heparin sodium 5,000 IU/mL solution for injection or concentrate for solution for infusion

This medicine contains 34 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1.7 % of the recommended maximum daily dietary intake of sodium for an adult.

### 3. How to use Heparin

Heparin infusion will be given to you by a doctor or a nurse. It will be injected into a vein either all at once or over a longer period of time, usually via a drip.

Your doctor will prescribe the right dose for you.

**To TREAT blood clots in leg veins (deep vein thrombosis), blood clots in the lung, (pulmonary embolism), chest pains (unstable angina pectoris) and severe blood clots in the arteries (acute peripheral arterial occlusion)**

#### **Adults**

The usual dose in adults is 5,000 units injected into a vein. This is followed by:

1,000-2,000 units/hour injected slowly into a vein or

5,000-10,000 units 4 hourly injected all at once into a vein

#### **Elderly**

Lower doses may be used in the elderly.

#### **Children and adolescents**

The usual dose is 50 units/kg body weight injected into a vein followed by:

15-25 units/kg body weight/hour injected slowly into a vein or

100 units/kg body weight 4 hourly injected all at once into a vein. You will have blood tests every day to check the effects of your heparin.

#### **During heart and lung surgery (Adults)**

Initially you will be given 300 units/kg per body weight. This will be changed according to the results of your blood tests.

#### **During kidney dialysis (Adults)**

Initially you will be given 1,000-5,000 units per hour. This will be changed according to the results of your blood tests.

#### **If you receive more heparin than you should:**

You may start to haemorrhage (bleed severely). Please read section 4 so you can spot any signs this may be happening to you.

You may be given another injection of a medicine called protamine sulphate.

### 4. Possible side effects

Like all medicines, Heparin infusion can cause side effects, although not everybody gets them.

Important side effects to look out for include:

- You have difficulty breathing, wheezing
- Fever, chills

- Your face or throat swell
- Your skin develops a severe itchy rash
- Your skin develops blisters at the site of your injection
- You develop blue tinge to the lips
- Swelling of eyes and lips
- Shock
- Eye irritation
- Runny nose

**You must get urgent medical help if you have any of the above symptoms. You may be having an allergic reaction.**

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

- Tingling, weakness or numbness in your legs or lower body
- Back pain
- Incontinence of urine or incontinence from back passage or other problem in those areas

**If you are concerned about unusual bleeding you must tell your doctor or nurse immediately as heparin may need to be stopped.**

Signs that you are bleeding more easily include:

- Blood in your urine (which may cause this to go dark)
- Black tarry stools
- Unusual bruising or purple spots on your skin
- Bleeding that will not stop from any operation site or other injury
- Unusual bleeding from your gums
- Unusual nose bleeds

### **Reduction in the number of cells that help your blood clot (thrombocytopenia)**

Thrombocytopenia may result in the formation of dangerous blood clots causing chest pains, shortness of breath, coughing, feeling faint, dizziness or loss of consciousness.

**You must tell your doctor or nurse immediately.**

If thrombocytopenia develops, heparin treatment should be stopped immediately.

Thrombocytopenia can occur up to several weeks after the end of your heparin treatment. As such, your doctor may take a blood test in that time.

### **Other possible side effects**

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

- Bruising at the site of the injection.
- Irritation at the site of the injection.
- Collection of blood outside of a blood vessel (haematoma).
- Changes in your blood test results (raised transaminase, lipid level, potassium). Your doctor can explain this more.

**Uncommon side effects** (probably affect less than 1 in 100 people)

- Rash.
- Itchy raised rash (hives).
- Osteoporosis. Your bones become less strong and can break more easily. This has been seen in patients taking heparin for a long time.

- Loss of hair (alopecia) with prolonged dosing with heparin.

**Rare side effects** (probably affect less than 1 in 1,000 people)

- Local skin necrosis - complication that results in death of the skin tissue.

**Very rare side effects** (probably affect less than 1 in 10,000 people)

- Priapism: prolonged, painful erections in men.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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](http://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: 4 years

This medicinal product does not require any special storage conditions.

Do not freeze.

Chemical and physical in use stability has been demonstrated for 28 days at 25°C.

From a microbiological point of view, once opened, the product may be stored for a maximum of 28 days at 25°C. Other in use storage times and conditions are the responsibility of the user.

Shelf-life after dilution

The stability of mixtures of Heparin Sodium 1000 IU/ml and Heparin Sodium 5000 IU/ml at a concentration of 47.6 IU/ml and 455 IU/ml at 25°C ± 2°C for 72 hours with glucose diluents at 5 % or 0.9% NaCl.

Medicines should not be thrown away in waste water or in household waste. Please ask your pharmacist how to throw away any medicine you do not need anymore. If you do this you will help protect the environment.

## 6. Contents of the pack and other information

**What heparin injection 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 include sodium methylparaben (E-219), sodium propylparaben (E-217), sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

Each multidose vial should be restricted to use in a single patient.

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 1, 5 and 10 vials of heparin 1,000 and 5,000 IU/ml in a carton.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Reig Jofre UK Ltd,

Follaton House, Plymouth Road, Totnes, Devon, TQ9 5NE, UK

Manufacturer:

Laboratorio Reig Jofre, S.A.

Gran Capitan, 10

08970 Sant Joan Despí

Barcelona

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