



Heparin Sodium Injection USP 1000 Units/1ml, 5000 units/5ml, 25000 units/5ml

Package leaflet: information for the user

Heparin sodium 100 IU/ml I.V. flush solution

heparin sodium

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.
- If any of the side effects become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- 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 Sodium Injection is and what it is used for
2. What you need to know before you use Heparin Sodium Injection
3. How to use Heparin Sodium Injection
4. Possible side effects
5. How to store Heparin Sodium Injection
6. Contents of the pack and other information

1. What Heparin Sodium Injection is and what it is used for

Heparin Sodium Injection belongs to a group of medicines called anticoagulants. It helps to stop the blood from clotting.

Heparin Sodium Injection is given into an intravenous (I.V.) line. This means it is injected into the tube connected to a vein to keep it clear by preventing the blood from clotting in it.

It is not recommended for treatment of harmful blood clots in your body.

2. What you need to know before you have Heparin Sodium Injection

Do not have Heparin Sodium Injection

- If you are allergic (hypersensitive) to heparin 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).

Do not give this medicine to a premature baby, a newborn baby, or a baby up to a month old.

Take special care with Heparin Sodium Injection

Before you have Heparin Sodium Injection , tell your doctor:

- If you are pregnant or think you are pregnant. Read the section "Pregnancy and breast-feeding".
- If you are allergic (hypersensitive) to low molecular weight heparins, such as tinzaparin, enoxaparin or dalteparin.
- If this medicine is for a child who is between one month and three years old.
- If you know that you are sensitive to methylparahydroxybenzoate or propylparahydroxybenzoate. Read the information in the section "Important information about some of the ingredients of Heparin Sodium Injection".

If you have Heparin Sodium Injection regularly for more than five days, your doctor may take regular blood tests. This is to check the level of platelets (a type of cell) in your blood while you have your medicine.

Depending on the result the doctor may tell you to stop having this medicine straight away.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines. This includes any medicines which you have bought without a prescription.

Pregnancy and breast-feeding

Unless your doctor has told you it is essential, you must not have Heparin Sodium Injection if you are pregnant, or think you are pregnant.

Read the information about benzyl alcohol in the section "Important information about some of the ingredients of Heparin Sodium Injection". If you are pregnant or might be pregnant, tell your doctor before you are given Heparin Sodium Injection.

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

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

Driving and using machines

Usually your medicine may have little 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 Sodium Injection

This medicine contains:

- Benzyl alcohol. This is a preservative. It may harm a newborn baby. It must not be used in premature babies or babies under one month old.
- Methylparahydroxybenzoate and propylparahydroxybenzoate. These are preservatives. They may give you an allergic reaction. 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.



- Sodium. This medicine is nearly “sodium free”. Your medicine contains less than 23 milligrams (mg) of sodium in each 100 International Units (IU) dose.

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

3. How to use Heparin Sodium Injection

Heparin Sodium Injection will be given to you by a doctor or nurse. Heparin Sodium Injection should not be mixed with any other injection.

The recommended dose of Heparin Sodium Injection is

2 ml containing 200 IU of heparin should be administered into the catheter/cannula every 4-8 hours or as required. Your doctor will prescribe the right dose for you.

If you take more Heparin Sodium Injection 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.

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

4. Possible side effects

When used as recommended the low dose of heparin reaching the blood is unlikely to have any effects on the body. However, information is given here on possible side effects.

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 an allergic reaction:

- You have difficulty breathing, wheezing
- Your face or throat swell
- Your skin develops a severe rash
- Hives
- Fever, chills
- Swelling of eyes and lips
- You develop blue tinge to the lips

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, mouth or any operation wound that will not stop.

Other possible side effects

- Bruising or bleeding more easily. Your blood may also form harmful clots. A big drop in clotting cells (platelets) in your blood may give you these symptoms. Your doctor can explain this more.



Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed on this leaflet.

5. How to store Heparin Sodium Injection

- Keep out of the sight and reach of children.
- Do not use Heparin Sodium Injection after the expiry date on the label. The expiry date is the last day of that month.
- Store below 25°C.

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 Sodium Injection contains

- The active ingredient is heparin sodium. This product contains 100 IU of heparin sodium in each millilitre (ml).
- The other ingredients are benzyl alcohol, methylparahydroxybenzoate, propylparahydroxybenzoate, sodium chloride, sodium citrate 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 Sodium Injection looks like and contents of the pack

Heparin Sodium Injection is a clear, colourless or pale yellow liquid. This medicine comes in glass ampoules containing 2 ml. There are 10 ampoules in a carton.

7. Manufactured in India by: TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214. Old Bake House,
Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001
at: Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m. EST

E-mail: tajgroup@tajpharma.com