Heparin 5,000 I.U./ml

Solution for injection

Heparin sodium

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

1. What Heparin 5,000 I.U./ml is and what it is used for

The name of this medicine is Heparin 5,000 I.U./ml. It is an anticoagulant. Heparin prevents blood clotting.

Heparin contains benzyl alcohol which may cause bronchospasm.

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

2. What you need to know before you are given Heparin 5,000 I.U./ml

You should not be given Heparin 5,000 I.U./ml if you:

- are allergic to heparin or any of the other ingredients of this medicine (listed in section 6);
- are pregnant;
- bleed or bruise easily;
- have had severe skin problems resulting from previous heparin treatment;
- are likely to bleed more.

Taking some medicines at the same time as heparin may mean you may be likely to bleed more.

In particular, tell your doctor if you are taking any of the following:

- Aspirin or other non-steroidal anti-inflammatory drugs (e.g. diclofenac or ibuprofen);
- Medicines which may interfere with the proper clotting of the blood (e.g. diprydamole, epoprostenol, clopidogrel or streptokinase);
- Medicines that may increase the potassium level in your blood, e.g. acetazolamide, colchicine.

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

If you have any doubts about whether this medicine should be administered then discuss things more fully with your doctor or nurse before Heparin 5,000 I.U./ml is given.

3. How Heparin 5,000 I.U./ml is given

Your doctor or nurse will inject your dose of heparin into a vein either all at once or over a longer period of time (usually via a drip). Alternatively they may inject your heparin underneath your skin.

The amount injected all at once into a vein should not be greater than 15 ml.

You may need to have blood tests if you are receiving higher doses of heparin to check on the effects of your heparin treatment.

Heparin injection must not be given to premature or newborn babies.

You may require a lower dose if you have kidney or liver disease.

To prevent blood clots in leg veins (deep vein thrombosis) and blood clots in the lung (pulmonary embolism).

Adulthood

The usual dose of heparin injection in adults is 5,000 units injected under the skin 2 hours before your operation, followed by a constant drip. Alternatively they may inject your heparin underneath your skin.

The amount injected all at once into a vein should not be greater than 15 ml.

Elderly

Lower doses may be used in the elderly. You may need to have blood tests if you are elderly, to check on the effects of your heparin treatment.

You may need to have blood tests if you are receiving higher doses of heparin to check on the effects of your heparin treatment.

4. Possible side effects

Your doctor or nurse will inject your dose of heparin into a vein either all at once or over a longer period of time (usually via a drip). Alternatively they may inject your heparin underneath your skin.

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Elderly

Lower doses may be used in the elderly. You may need to have blood tests if you are elderly, to check on the effects of your heparin treatment.
The active substance is heparin sodium.

To prevent a blood clot in the heart following a heart attack.
You will have blood tests every day to check the effects of your heparin.

To treat 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
• 10,000-20,000 units 12 hourly injected under the skin or
• 5,000-10,000 units 4 hourly injected all at once into a vein.

Elderly
Lower doses may be used in the elderly.

Small adults and children
Small adults and children will be given 50 units/kg body weight injected into a vein followed by:
• 15-25 units/kg body weight/hour injected slowly into a vein or
• 250 units/kg body weight 12 hourly injected under the skin or
• 100 units/kg body weight 4 hourly injected all at once into a vein

To treat 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 maybe used in the elderly.

Small adults and children
Small adults and children will be given 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.

To prevent a blood clot in the heart following a heart attack.

Adults
The usual dose for adults is 12,500 units 12 hourly injected under the skin for at least 10 days.

Elderly
A lower dose may be needed.

During Heart and Lung Surgery (Adults)
Initially you will be given 300 units/kg 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. This will be changed according to the results of your blood tests.

If you think you have been given too much Heparin 5,000 I.U./ml
Your doctor will decide which dose is best for you.

Too much heparin can cause bleeding. Slight bleeding can be stopped by stopping your heparin treatment. However if you have more severe bleeding you may need blood tests and an injection of a medicine called protamine sulphate.

If you think too much medicine has been given to you, contact your doctor or nurse.
If you have any further questions on the use of this medicine, ask your doctor or nurse.

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

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

Important side effects to lookout for (frequency not stated):

Severe allergic reactions
Heparin can cause a severe allergic reaction with wheezing, difficulty breathing, a blue tinge to the lips, fever, chills, swelling of the eyes and lips and shock.

If you think you are having a severe allergic reaction you must stop receiving heparin and tell your doctor or nurse immediately.

Bleeding and Bruising
Signs that you are bleeding more easily include:
• unusual bruising or purple spots on your skin,
• unusual bleeding from your gums,
• unusual nose bleeds,
• blood in your urine (which may cause this to go dark),
• black, tarry-looking stools,
• bleeding that will not stop from any operation site or other injury.

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

Other side effects (frequency not stated) include:
• red lumps or red, itchy patches like eczema often develop 3-21 days after the start of heparin treatment, where injections have been given under the skin,
• sloughing of skin may occur around the injection site,
• persistent erection of the penis,
• abnormal results for blood tests that report on how the liver is working,
• high level of blood fats after stopping heparin,
• high or low blood potassium. If affected you may feel tired and weak.

If heparin injection is given over many months then the following may occur:
• loss of hair,
• thinning of the bones (osteoporosis).

Reporting of side effects
If you get any side effects, talk to your doctor or, pharmacist 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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Heparin 5,000 I.U./ml
Keep this medicine out of the sight and reach of children.
Your doctor or nurse will usually be responsible for storing and preparing injection before use and for checking that the vials have not passed their expiry date stated on the carton and the label. This medicine must not be used after the expiry date which is stated on the carton and the label. The expiry date refers to the last day of that month.

Heparin injection should not be given if it shows signs of deterioration such as discolouration.

After reconstitution:
Chemical and physical in-use stability after reconstitution in glucose 5% and in 0.9% sodium chloride solution has been demonstrated for 48 hours at 18-22°C.

Do not throw away any medicines via wastewater 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 5,000 I.U./ml contains
– The active substance is heparin sodium
– Each vial with 5 ml solution for injection contains 25,000 I. U. of heparin sodium.
– The other ingredients are benzyl alcohol, sodium hydroxide, hydrochloric acid, water for injections.

What Heparin 5,000 I.U./ml looks like and contents of the pack
Heparin 5,000 I. U./ml is available in packs of 10 vials.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
PANPHARMA
Z.I. du Clairay
35133 Luiré
France

Manufacturer
PANPHARMA GmbH
Bunsenstrasse 4
22946 Trittau
GERMANY

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