

BEPRIN (HEPARIN SODIUM) SOLUTION FOR INJECTION

5000 IU/ML

1000IU/ML

Package leaflet:

Information for the patient

Beprin (Heparin sodium) 5,000 IU/ml Solution for injection

Beprin (Heparin sodium) 1,000 IU/ml Solution for injection

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 or pharmacist.
- 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 pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

The name of your medicine is either heparin sodium 5,000 I.U./ml, or heparin sodium 25,000 I.U./5ml solution for injection or concentrate for solution for infusion. In the rest of this leaflet it is called Beprin injection.

What is in this leaflet

- 1. What Beprin Injection is and what it is used for**
- 2. What you need to know before you take Beprin Injection**
- 3. How to take Beprin Injection**
- 4. Possible side effects**
- 5. How to store Beprin Injection**
- 6. Contents of the pack and other information**

1. WHAT BEPRIN INJECTION IS AND WHAT IT IS USED FOR

Heparin belongs to a group of drugs that are called anti-coagulants. These help to stop blood clotting. Beprin injection is used in conditions where blood vessels may become blocked by blood clots. It is therefore used to treat and prevent:

- 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)
- the prevention of blood clots in the heart following a heart attack (mural thrombosis).

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BEPRIN INJECTION

Beprin injection should not be given if you:

- are allergic to heparin or any of the other ingredients of this medicine (listed in section 6)
- drink large amounts of alcohol
- are currently bleeding from anywhere in the body, (apart from your normal periods which do not stop you being given heparin injection)
- have haemophilia (a genetic disorder which may cause you to bleed excessively) or any other bleeding problem
- have or have ever had thrombocytopenia (a serious blood disorder which prevents blood from clotting properly)
- bruise easily (fragile capillaries) or have lots of purple spots that look like bruises (purpura)
- have very high blood pressure
- are suffering from tuberculosis (TB)
- have had severe skin problems resulting from previous heparin treatment

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- are about to have surgery of the brain, spine or eye, a lumbar puncture or local anaesthetic nerve block, or some other procedure where bleeding could be a problem
- have recently had an operation
- suffer from severe liver problems which can lead to bleeding into the oesophagus (gullet)
- have bleeding into the brain.

Warnings and precautions

Talk to your doctor before Beprin injection is given if you:

- are over 60 years of age
- have any condition which makes you 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), a stroke, cancer or threatened miscarriage). If you are unsure, ask your doctor or nurse.
- suffer from diabetes
- suffer from excess acid or high levels of potassium in your blood or are taking a 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
- have kidney or liver disease. Your doctor may decide that a lower dose is necessary
- suffer from allergies or have previously had an allergic reaction to low molecular weight (LMW) heparin. A small test dose of heparin sodium injection may be given first. Your doctor will check your blood if you receive treatment for longer than five days and may do other blood tests if you have major surgery.

Your doctor will take particular care if:

- you have an epidural or an anaesthetic given into the spine.

Other medicines and heparin injection

Tell your doctor if you are taking, have recently taken or might take any other medicines, including those medicines obtained without a prescription, as some medicines may affect the way heparin injection works. Taking some medicines at the same time as heparin could 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 antiinflammatory drugs (e.g. diclofenac or ibuprofen)
- dextran solutions (used to treat shock)
- medicines which may interfere with the proper clotting of the blood (e.g. dipyridamole, epoprostenol, clopidogrel or streptokinase)
- cephalosporins, used to treat infections
- medicines called ACE inhibitors used for high blood pressure and heart failure (e.g. captopril, enalapril, lisinopril or ramipril)
- medicines that may increase the potassium level in your blood (e.g. amiloride, triamterene, eplerenone or spironolactone)
- glyceryl trinitrate given into a vein (for coronary heart disease)
- aminoglycoside antibiotics (e.g. gentamicin, amikacin, neomycin or tobramycin)
- probenecid, used in the treatment of gout

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 it is given.

Tobacco smoke can also interfere with the working of heparin injection. 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, breast-feeding and fertility

You should let your doctor or nurse know before you are given heparin injection if you are pregnant or wish to become pregnant.

If you are being given heparin injection 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.

Ask your doctor or nurse for advice if you wish to breast-feed

Driving and using machines

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

3. HOW TO TAKE BEPRIN INJECTION

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.

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

Adults

The usual dose of heparin injection in adults is 5,000 units injected under the skin 2 hours before your operation, followed by 5,000 units injected under the skin every 8-12 hours, for 7-10 days or until you are fully able to move about.

Pregnancy

During pregnancy the dosage is 5,000- 10,000 units injected under the skin every 12 hours. The dose may be adjusted according to your blood tests.

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.

Children

No specific doses are recommended.

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

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

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 per hour. This will be changed according to the results of your blood tests.

If you think you have been given too much heparin injection

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 sulfate. If you think too much medicine has been given to you contact your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, beprin injection can cause side effects in some patients, although not everybody gets them. These are most likely to occur when treatment is first started. You should inform your doctor or nurse immediately if you feel unwell.

Important side effects to look out for:

- Severe allergic reactions
- allergic reactions including an itchy skin rash, eye irritation, runny nose, wheezing, rapid 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 (see symptoms above) you must tell your doctor or nurse immediately

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• Bleeding and Bruising

Heparin injection can reduce the number of cells that help your blood clot (thrombocytopenia) and so can cause bleeding and bruising. This is most likely to occur within the first few days of treatment but may occur later too. The risk of bleeding is increased in the elderly (particularly elderly women).

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.

Other side effects include:

Common: may affect up to 1 in 10 people

- 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

Rare: may affect up to 1 in 1,000 people

- raised levels of potassium in the blood, particularly in patients with kidney failure or diabetes. If affected you may feel tired and weak.
- irritation or sloughing of skin may occur around the injection site.

Not known; frequency cannot be estimated from the available data

- loss of hair (alopecia) if heparin sodium injection is given over many months
- weakening of the bones (osteoporosis) if heparin sodium injection is given over many months

- persistent erection of the penis (priapism)
- abnormal liver tests
- the amount of a hormone called aldosterone may be lower than normal Your doctor can explain this more.
- high lipid levels on stopping heparin

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.

5. HOW TO STORE BEPRIN INJECTION

Keep this medicine out of the sight and reach of children.

Your doctor or nurse will usually be responsible for storing and preparing heparin injection before use and for checking that the vials have not passed their expiry date stated on the carton and the label. Do not use this medicine 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.

Do not store above 25°C. Store in the original packaging in order to protect the product from light.

After opening, heparin ampoules must be used immediately. Any portion of the contents not used at once should be discarded.

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 FURTHER INFORMATION

What Beprin Injection contain

The active substance is heparin sodium.
The other ingredients include water for injections, hydrochloric acid and sodium hydroxide.

1ml of solution of beprin sodium injection 1,000 I.U./ml contains 1,000 international units of the active ingredient. It is available in 5ml multidose vials containing 5,000 I.U. in 5ml of solution.
The other ingredients include benzyl alcohol (10mg/ml), methyl parahydroxybenzoate (E218) (as preservatives), water for injections, hydrochloric acid and sodium hydroxide.

What Beprin Injection look like and contents of the pack

Beprin injection is a colourless or strawcoloured liquid.

Manufactured by:

Taj Pharmaceuticals Limited

220, Mahagujarat Ind. Estate, Moraiya, Tal. Sanand, Dist. Ahmedabad, Gujarat, INDIA