

Package leaflet: Information for the patient

Heparin Sodium BP 2000 IU/L in 0.9% w/v Sodium Chloride IV Infusion

Active substance: Heparin Sodium

Read all of this leaflet carefully before you are given 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, nurse or pharmacist.

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Throughout this leaflet, Heparin Sodium BP 2000 IU/L in 0.9% w/v Sodium Chloride IV Infusion will be called Heparin Sodium Solution.

What is in this leaflet:

1. What Heparin Sodium Solution is and what it is used for
2. What you need to know before you are given Heparin Sodium Solution
3. How you will be given Heparin Sodium Solution
4. Possible side effects
5. How Heparin Sodium Solution is stored
6. Contents of the pack and other information

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

Heparin Sodium Solution contains a medicine called heparin. It belongs to a group of medicines called antithrombotics or anticoagulants, they stop your blood from clotting.

Heparin Sodium Solution is used to:

- stop blood clotting when it is removed from your body, for example during dialysis. Dialysis is used to help your kidneys remove toxins from your blood
- stop tubes that are put into your blood vessels (catheters) from getting blocked by blood clots.

2. What you need to know before you are given Heparin Sodium Solution

Your doctor will not give you Heparin Sodium Solution if:

- you have low levels of platelets in your blood. Platelets are part of your blood (thrombocytopenia)
- your doctor has diagnosed you with heparin-induced thrombocytopenia (HIT), a type of immune system response or if you have been tested and have HIT antibodies.
- you tend to have difficulty in stopping bleeding
- you are allergic (hypersensitive) to the active ingredient or any of the other ingredients of Heparin Sodium Solution (listed in section 6)

You will not be given Heparin Sodium Solution if any of the above applies to you. If you are not sure if you have any of these conditions, talk to your doctor, nurse or pharmacist before having Heparin Sodium Solution.

Warnings and Precautions

Talk to your doctor, nurse or pharmacist before being given Heparin Sodium Solution. You should not be given this medicine if the container is damaged. You should not be given this medicine by mouth (orally)

Your doctor will take special care with this medicine if:

- you have an increased risk of bleeding (haemorrhage), including:
 - illness related to your heart, which causes very high blood pressure (Severe hypertension) or inflammation of the heart, due to infection (Subacute bacterial endocarditis)
 - you have had surgery recently
 - you have an illness which causes bleeding, such as haemophilia or thrombocytopenia
 - you have ulcers in your stomach or intestines
 - you have an antithrombin III deficiency, inherited from your parents
 - you have liver disease
 - you have an indwelling catheter (a type of tube in your body)
 - you are menstruating

Your doctor may give you a test to check your blood cells
- you develop heparin-induced thrombocytopenia (HIT), a type of immune system response. Your doctor will stop using this medicine if they think you might have HIT. You may also have tests to check your antibodies (part of your immune system) and to check the levels of something called platelets in your blood.
- you develop low levels of platelets in your blood. Platelets are part of your blood.
- you develop Heparin resistance. This means that the Heparin does not work as well as it usually would. Your doctor may adjust your dose.
- you feel cold, have a fever, you have problems breathing or you get a rash: these may all be signs of hypersensitivity (intolerance).
- your blood vessels get smaller, quickly (vasospasm) which might make a limb, such as your arm or leg, painful. Your limb may also change colour, becoming bluer. You may also have a headache.
- you have high levels of potassium in your blood (hyperkalaemia), especially if you have diabetes or kidney problems. Your doctor should measure your potassium levels if they think you have a risk of high levels of potassium in the blood.
- you have too much fluid in your body, especially if you have a sensitivity to sodium, for example, because of heart failure or kidney problems. Your doctor may monitor changes in your fluid balance and electrolyte concentrations (electrolytes are salts and minerals).
- you are over 60 years old, especially if you are a woman.

Your doctor should be careful in how they set up the container to avoid risks of air embolism. Air embolism is when air is trapped in your blood vessel.

Your doctor should be careful to consider the levels of potassium in your blood to make sure your potassium levels do not become too low (hypokalaemia). This can happen when people are given too much fluid by vein, without potassium.

If any of the above apply to you (or you are not sure), check with your doctor, nurse or pharmacist before being given this medicine. You may need to be checked carefully and your treatment may be changed.

Other medicines and Heparin Sodium Solution

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you have obtained yourself, without a prescription, including herbal medicines and natural products. Your doctor will check that any other medicines you are taking will not alter the way that Heparin Sodium Solution works.

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

- warfarin or dicoumarol, because they may affect the results of some blood tests that are used to check how well your blood clots
- drugs which may cause bleeding or stop blood clotting properly such as:
 - NSAIDS (acetylsalicylic acid, ibuprofen, indomethacin, and celecoxib)
 - epoprostenol
 - clopidogrel
 - thienopyridines
 - dipyridamole
 - hydroxychloroquine
 - glycoprotein IIb/IIIa antagonists (including abciximab, eptifibatide, and tirofiban)
- antithrombin III: if you have an antithrombin III deficiency, inherited from your parents, you may need a lower dose of this medicine.
- tobacco and nicotine: if you smoke you may need a higher dose of this medicine.
- intravenous nitroglycerin: your doctor will need to monitor you if you are given intravenous nitroglycerin.
- medicines that lower the amount of potassium that passes into your urine, such as certain medicines used to treat high blood pressure, called ACE inhibitors or Angiotensin-II antagonists.
- medicines that contain corticosteroids or corticotrophin such as those used to treat asthma and some allergic reactions, as the sodium in Heparin Sodium Solution may interfere with the action of these.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before being given Heparin Sodium Solution.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor if you are pregnant or breastfeeding. They will advise you if this treatment is suitable for you. Heparin is not excreted in human milk, and can be used during breastfeeding

Driving and using machines

Heparin Sodium Solution has little or no influence on the ability to drive or use machines. Please inform your doctor and they will advise you if you can drive or use machines.

3. How you will be given Heparin Sodium Solution

The recommended dose

Your doctor will decide how much of the medicine you will need and for how long it will be given to you. This will depend on:

- your age and weight
- the reason you are being given the medicine
- if it is being given to you to keep your catheter clear, the dose will depend on the type of catheter you have.

How Heparin Sodium Solution is given

The solution will be given as a slow injection (infusion) through a plastic tube (catheter) which will be placed carefully into your vein by a doctor or nurse. Heparin Sodium Solution is not effective if given orally.

If you have too much Heparin Sodium Solution

It is unlikely that you will be given more Heparin Sodium Solution than you should, because it will be given to you by a trained and qualified person. If you are given too much of this medicine, however, you may get nosebleeds, blood in the urine, tarry stools or bruise easily. If you get these symptoms please speak to your doctor or nurse and they will check.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

4. Possible Side Effects

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

Tell your doctor, nurse or pharmacist straight away if you notice any of the following side effects, which can be serious. The infusion may also need to be stopped.

Frequency not known

Internal bleeding (adrenal and/or ovarian haemorrhage) may cause death, if not recognised.

- immune system disorders:
 - intolerance to the medicine (hypersensitivity, including anaphylactic shock, anaphylactoid reaction)
 - asthma
 - chills
 - fever
 - rash or hives (urticaria)
 - stuffy nose (rhinitis)
 - watery eyes (lacrimation)
 - headache
 - feeling sick (nausea)
 - being sick (vomiting)
 - itching
 - burning
- metabolism and nutrition disorders:
 - high levels of lipids (rebound hyperlipidemia or hyperlipidemia)
 - high levels of potassium in the blood (hyperkalaemia)
- reproductive system and breast disorders
 - prolonged painful erection (priapism)
 - ovarian cyst (corpus luteum haemorrhage)
- general disorders and administration site conditions:
 - irritation
 - redness of the skin (erythema)
 - mild pain
 - blood or ulcer in the area of injection (hematoma or ulceration)
- investigations
 - in tests: increased aspartate aminotransferase
 - in tests: increased alanine aminotransferase

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.

Ireland: You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine

5. How Heparin Sodium Solution is stored

Keep out of the sight and reach of children.

Hospital staff will ensure that the product is stored and disposed of correctly and not used after the expiry date stated on the product label after EXP. The expiry date refers to the last day of that month

- do not store above 25°C.
- Heparin Sodium Solution must not be used if the container is damaged or the solution is not clear.

The solution should only be used once. Any left over solution should be discarded.

Do not throw 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 Sodium Solution contains

The active substances are heparin sodium 2,000 International Units (IU) in each litre (L), sodium chloride (9 g/L), disodium phosphate dodecahydrate (5.8 g/L) and citric acid monohydrate (405 mg/L).

The other ingredient is sterile water (called ‘water for injections’).

What Heparin Sodium Solution looks like and contents of the pack

It is supplied as a clear solution for infusion (slow injection) in a 500 ml VIAFLEX plastic bag with a plastic overpouch. Do not remove from overpouch until ready for use.

Marketing Authorisation Holder and Manufacturers

The Marketing Authorisation holder is:

Baxter Holding B.V.

Kobaltweg 49,
3542CE Utrecht,
Netherlands

Send all enquires to this address.

Heparin Sodium Solution can be made at any of these addresses:

Bieffe Medital SpA
Via Nuova Provinciale - 23034 Grosotto (SO)
Italy

Baxter Healthcare S.A.
Castlebar, Co. Mayo

Ireland

This leaflet was last revised in August 2021.

Other sources of information

For information about Heparin Sodium Solution or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 (0)1635 206345.

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