

Package leaflet: Information for the patient

Heparin Sodium BP 1000 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 1000 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 are allergic (hypersensitive) to the active ingredient or any of the other ingredients of Heparin Sodium Solution (listed in section 6)
- you tend to have difficulty in stopping bleeding.

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.

Your doctor will take special care with this medicine if:

- you have kidney or heart problems
- you are at risk of losing large amounts of blood (haemorrhage)
- you have high blood pressure

Also you need to be checked carefully and you may need a blood potassium test to make sure Heparin Sodium Solution is suitable for you if:

- you have kidney problems, diabetes or too much acid in your blood (metabolic acidosis)
- you have ever been told by your doctor that you have too much potassium in your blood.

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:

- medicines that change the way your blood clots such as aspirin or ibuprofen
- warfarin or dicoumarol, because they may affect the results of some blood tests that are used to check how well your blood clots
- 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 having Heparin Sodium Solution.

Tests you may have while Heparin Sodium Solution is used

Your doctor may want to check:

- your blood potassium level before treatment if you have certain conditions (see 'Warnings and Precautions' for more information)
- your blood potassium level during treatment, if your treatment is going to last longer than
- 7 days
- your blood levels of other substances called 'electrolytes', such as sodium. If you are having difficulty breathing or have swollen legs and arms.
- the level of red blood cells in your blood
- for traces of blood in your stools.

Pregnancy and breast-feeding

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

Tell your doctor if you are pregnant or breast-feeding. They will advise you if this treatment is suitable for you.

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. They will discontinue the infusion straightaway if too much was given.

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.

- allergic reaction, the signs may include high temperature, rash, watery and red eyes
- or wheezing, headache, nausea and vomiting. If you have a reaction to the medicine, it will be stopped
- nose bleeds, unusual bruising or blood in your urine. This may mean you have been given too much Heparin Sodium Solution.
- temporary hair loss
- brittle bones (osteoporosis)
- it is also possible that your blood will not clot properly for a short time after having this medicine
- rarely, high potassium levels in your blood (usually only seen in blood tests) particularly if you have diabetes or kidney problems.

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.

UK: You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard

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 1,000 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, in Ireland (ROI) is:

Baxter Holding B.V.

Kobaltweg 49,

3542CE Utrecht,

Netherlands

Send all enquires to this address.

The Marketing Authorisation holder, in the UK, is:

Baxter Healthcare Ltd
Caxton Way, Thetford
Norfolk, IP24 3SE
United Kingdom
Send all enquires to this address.

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

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

Baxter Healthcare S.A.
Castlebar, Co. Mayo
Ireland

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

Baxter Healthcare Ltd
Caxton Way, Thetford
Norfolk, IP24 3SE
United Kingdom

Baxter Healthcare S.A.
Castlebar, Co. Mayo
Ireland

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

This leaflet was last revised in May 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.

Baxter and Viaflex are trademarks of Baxter International Inc.