

DBL™ Heparin Sodium Injection BP

Heparin (HEP-a-rin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Heparin Sodium Injection BP.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given heparin against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What DBL™ Heparin Sodium Injection BP is used for

This medicine is used for the prevention and treatment of disorders caused by blood clots, such as certain heart, blood vessel and lung conditions. It is also used to prevent blood clots from forming during some types of surgery, dialysis and blood transfusions.

This medicine belongs to a group of medicines called anticoagulants.

It works by decreasing the clotting ability of the blood.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

Before you are given DBL™ Heparin Sodium Injection BP

When you must not be given it

You should not be given DBL™ Heparin Sodium Injection BP if you have an allergy to:

- any medicine containing heparin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

You should not be given this medicine if you have any of the following medical conditions:

- conditions where bleeding is or may be a problem, such as haemophilia, hiatus hernia, bleeding haemorrhoids (piles)
- retinopathy (a disease of the retina)
- problems with fragile blood vessels
- endocarditis (inflammation of the lining of the heart)
- ascorbic acid (Vitamin C) deficiency
- very high blood pressure
- stomach or intestinal ulcers or other conditions which may bleed, such as ulcerative colitis
- severe kidney or liver disease

- major surgery involving the eyes, brain or spinal cord
- immediately after childbirth
- low blood platelet count (thrombocytopenia)
- a drop in blood platelet count due to heparin or pentosan polysulfate.

If you are not sure whether you should be given this medicine, talk to your doctor.

Premature or low birth weight babies should not be given DBL™ Heparin Sodium Injection BP 35,000 IU/35 mL vials as these contain benzyl alcohol.

Note that the DBL™ Heparin Sodium Injection BP ampoules do not contain benzyl alcohol.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- asthma
- liver or kidney disease
- high blood pressure (hypertension)
- ulcer disease
- vascular disease
- recent dental procedures.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given heparin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and heparin may interfere with each other. These include:

- other anticoagulants (such as warfarin) which also prevent blood clots
- aspirin or other non steroidal anti-inflammatory drugs (NSAID's)
- dipyridamole (a medicine for heart problems)
- systemic corticosteroids eg prednisolone, hydrocortisone.

These medicines may be affected by heparin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being given heparin.

How DBL™ Heparin Sodium Injection BP is given

How much is given

Your doctor will decide what dose of heparin you will receive and how long you will receive it for. This depends on your condition and other factors, such as your weight and results of blood tests.

How it is given

DBL™ Heparin Sodium Injection BP is given as an injection under the skin (subcutaneously) or as a slow injection into a vein (intravenously). It should not be given as an injection into a muscle (intramuscularly).

This medicine must only be given by a doctor, nurse, or other trained person.

If you have too much (overdose)

As DBL™ Heparin Sodium Injection BP is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given this medicine, tell your doctor or nurse immediately, or, if you are not in hospital, go to the Accident and Emergency department at your nearest hospital.

You may need urgent medical attention.

Please contact the Poisons Information Centre in Australia on 13 11 26 or in New Zealand on 0800 764 766 for advice on overdose management.

If you are given too much heparin, you may experience bleeding.

While you are being given DBL™ Heparin Sodium Injection BP

Things you must do

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are being given heparin.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

If you become pregnant while being treated with this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are being given this medicine.

It may interfere with the results of some tests.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given heparin.

This medicine helps to prevent or treat blood clots in most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 60 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, pharmacist or nurse to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- irritation, redness or mild pain at the injection site.

The above list includes side effects which are usually mild and short-lived.

This leaflet was updated in June 2014.

Tell your doctor or nurse immediately if you notice any of the following:

- easy bruising or bleeding (eg nose bleeds) during or after treatment
- passing blood in the urine or faeces
- dark coloured faeces
- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin, chills or fever
- changes to skin around the injection site
- moderate or severe pain at the injection site
- numbness, tingling or muscle weakness
- abnormal bowel or urinary function, or loss of control of bowel motions or urine.

The above list includes serious side effects which may require medical attention.

Tell your doctor or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given DBL™ Heparin Sodium Injection BP

Storage

DBL™ Heparin Sodium Injection BP will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

Product description

What it looks like

DBL™ Heparin Sodium Injection BP is a colourless or straw coloured solution for injection. It comes in glass ampoules or vials.

Ingredients

DBL™ Heparin Sodium Injection BP contains heparin sodium as the active ingredient. It also contains:

- water for injections
- benzyl alcohol (only in DBL™ Heparin Sodium Injection BP 35,000 IU/35 mL vials).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
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Level 3
500 Collins Street
Melbourne VIC 3000

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

DBL™ Heparin Sodium Injection BP is available in the following strengths and pack sizes:

- **Glass Ampoules:**
 - 1,000 IU/1 mL (5) - Aust R 12883
 - 5,000 IU/0.2 mL (5, 50) - Aust R 16349
 - 5,000 IU/1 mL (5) - Aust R 12881
- **Vials:**
 - 35,000 IU/35 mL (1) - Aust R 16345