

DBL™ Heparin Sodium Injection BP Ampoule

Heparin Sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Heparin Sodium Injection BP ampoule. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

This medicine is likely to be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases, this leaflet may be given to you after the medicine has been administered.

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 belongs to a group of medicines known as anti-coagulants. Anti-coagulants work by decreasing the clotting ability of the blood and help stop clots forming in the blood vessels.

Anti-coagulants are sometimes called "blood thinners", although they do not actually thin the blood. Heparin

will not dissolve blood clots that have already formed, but it may prevent any clots that have already formed from becoming larger and causing serious problems.

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

Heparin may be used for the treatment of other conditions that are not mentioned above. Your doctor will be able to tell you about the specific condition for which you have been prescribed heparin.

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.
- pork products

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 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
- stroke (bleeding on the brain)
- 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, or where a miscarriage is possible
- 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.

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 medical, surgical or dental procedures
- a heart infection, or other heart problems
- recent surgery on your eyes, brain or spinal cord

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

When heparin is used in pregnant women, it can cause premature (early) delivery or harm your baby. Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and heparin may interfere with each other. These include:

- pain relieving medicines such as aspirin and ibuprofen
- anti-inflammatory medicines such as indometacin and phenylbutazone
- anti-clotting medicines such as aprotinin, warfarin, dextran, abciximab, eptifibatide, tirofiban, streptokinase, urokinase, alteplase or anistreplase

- medicines to control bleeding such as andexanet alfa
- medicines for heart and circulation problems such as digitalis, glyceryl trinitrate, dipyridamole and epoprostenol
- systemic corticosteroids eg prednisolone, hydrocortisone.
- medicines for rheumatoid arthritis such as hydroxychloroquine
- medicines for treating gout such as probenecid
- medicines for reducing swelling of the body such as etacrynic acid
- medicines for hayfever such as anti-histamines
- nicotine
- medicines for cancer treatment such as cytostatic drugs and asparaginase (colaspase)
- antibiotics such as tetracyclines, cefamandole and penicillins
- medicines used for epilepsy (seizures) such as valproic acid
- medicines used for thyroid problems such as propylthiouracil
- substances used to enhance the contrast of structures or fluids within the body in medical imaging insulin or other medicines used to treat diabetes known as "sulfonylureas" such as glipizide, glimepiride, glyburide, tolazamide and tolbutamide
- medicines known as "benzodiazepines" such as chlordiazepoxide, diazepam, oxazepam
- propranolol.

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 on 131 126 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 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.

Things to be careful of

Be careful driving or operating machinery until you know how Heparin Injection affects you.

This medicine is not expected to affect your ability to drive a car or operate machinery. However, if you experience dizziness, light-headedness, tiredness or drowsiness, do not drive, operate machinery or do anything else that could be dangerous.

If you have any serious, physical accidents once you leave hospital, advise your treating doctor or nurse that you have been given this medicine recently.

Side effects

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

Like other medicines, heparin can cause some side effects. If they occur, most are likely to be minor or

temporary. However, some may be serious and need medical attention.

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

If you drink heavily you have a greater risk of bleeding compared to moderate drinkers or non-drinkers.

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 as soon as possible if you notice any of the following:

- change in skin colour, or pain around the injection site.
- fever
- chills
- runny nose
- watering eyes
- nausea and vomiting
- headache
- itchy soles of the feet

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

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

- any changes in skin colour or pain around the injection site, or the skin starts to swell, gets warm/red, becomes numb or starts to blister
- easy bruising or bleeding (eg. nosebleeds, heavy menstrual periods, bleeding from gums when brushing teeth) during or after treatment
- passing blood in the urine or faeces, dark coloured faeces, or vomiting blood
- 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

- numbness, pain, tingling or muscle weakness
- abnormal bowel or urinary function, or loss of control of bowel motions or urine.
- abdominal or stomach pain, chest pain, irregular, fast or fluttering heartbeat, muscle weakness or numbness in limbs, nausea and vomiting
- persistent painful erection

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 unwell.

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

Some side effects may only be seen by your doctor.

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.

Ingredients

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

- hydrochloric acid
- sodium hydroxide
- water for injections

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

Sponsor

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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AUST R 12881 - DBL Heparin
Injection 5,000 IU/1mL (5s)

AUST R 12883 - DBL Heparin
Injection 1,000 IU/1mL (5s, 50s)

AUST R 16349 - DBL Heparin
Injection 5,000 IU/0.2mL (5s, 50s)