

DBL™ HEPARIN SODIUM INJECTION (BP)

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or nurse.

1. Why am I being given DBL HEPARIN SODIUM INJECTION?

DBL HEPARIN SODIUM INJECTION contains the active ingredient heparin sodium, derived from pig intestines. It is used to prevent and treat blood clots in blood vessels that have started to clog up. It is also used to prevent clots from forming during and/or after surgery, kidney dialysis, blood transfusions or similar procedures, or if you have frostbite.

For more information, see Section [1. Why am I being given DBL HEPARIN SODIUM INJECTION?](#) in the full CMI.

2. What should I know before being given DBL HEPARIN SODIUM INJECTION?

Do not start treatment if you have ever had an allergic reaction to heparin or any medicine derived from heparin, pork products or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, especially those which involve increased risk of bleeding such as haemophilia, Vitamin C deficiency, fragile capillaries, hiatus hernia, retinopathy (eye disease), low platelet count, bleeding haemorrhoids (piles), very high/low blood pressure, heart infection, ulcers, liver/kidney disease, diabetes, cancer, allergies/asthma, or recently had a stroke, major surgery, given birth, are pregnant/breastfeeding or have heavy menstrual periods.

For more information, see Section [2. What should I know before being given DBL HEPARIN SODIUM INJECTION?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL HEPARIN SODIUM INJECTION and affect how it works. Heparin treatment may also lead to an increase of potassium in your blood, so you must tell your doctor if you are taking any other medicines, including those which raise your potassium levels. Also tell your doctor if you are a smoker or a heavy drinker (of alcohol).

A list of relevant medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is DBL HEPARIN SODIUM INJECTION given?

DBL HEPARIN SODIUM INJECTION is given by injection either under the skin or into a vein, or as a slow 'drip' into a vein.

Your doctor will decide what dose you will receive and for how long you will receive DBL HEPARIN SODIUM INJECTION. It must only be given by a doctor or a nurse.

- More instructions can be found in Section [4. How is DBL HEPARIN SODIUM INJECTION given?](#) in the full CMI.

5. What should I know during treatment with DBL HEPARIN SODIUM INJECTION?

Things you should do	• Tell your doctor if you notice any unusual bleeding, such as nose bleeds, bleeding gums after brushing your teeth, excessive bleeding at the injection site or from any open wounds. • If you need medical, dental/surgical procedures including blood test and contrast scans/x-rays in the next few weeks, tell your doctor, dentist, nurse or anaesthetist that you recently received heparin. • If you have any physical accidents once you leave hospital, seek medical attention and tell your treating doctor or nurse that you have recently been treated with DBL HEPARIN SODIUM INJECTION.
Driving or using machines	• In some cases, DBL HEPARIN SODIUM INJECTION may cause you to feel drowsiness, tiredness, dizziness, confusion or anxiety/agitation. If this occurs, do not drive or use machines.
Drinking alcohol	• Tell your doctor if you are a heavy alcohol drinker, as you would be at a greater risk of major heparin-associated bleeding than moderate or light drinkers.

For more information, see [5. What should I know during treatment with DBL HEPARIN SODIUM INJECTION?](#) in the full CMI.

6. Are there any side effects?

Side effects include: pain/bruising at injection site, allergic reaction, feeling sick/vomiting, unusual/increased bleeding, tingling/numbness or discolouration of hands/feet, abnormal heartbeat; muscle weakness, fever, severe back/tummy pain or headache, bleeding in tummy, gut, spine or brain, dizziness, osteoporosis, chest tightness/pain, difficulty breathing, stroke.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DBL™ HEPARIN SODIUM INJECTION (BP)

('hep-ah-rin soh-dee-um')

Active ingredient(s): *heparin sodium (from pig intestines)*

Consumer Medicine Information (CMI)

This leaflet provides important information about being treated with DBL HEPARIN SODIUM INJECTION.

You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about being treated with DBL HEPARIN SODIUM INJECTION.

Where to find information in this leaflet:

1. [Why am I being given DBL HEPARIN SODIUM INJECTION?](#)
2. [What should I know before being given DBL HEPARIN SODIUM INJECTION?](#)
3. [What if I am taking other medicines?](#)
4. [How is DBL HEPARIN SODIUM INJECTION given?](#)
5. [What should I know during treatment with DBL HEPARIN SODIUM INJECTION?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given DBL HEPARIN SODIUM INJECTION?

DBL HEPARIN SODIUM INJECTION contains the active ingredient heparin sodium, which is derived from pig intestines.

It belongs to a group of medicines known as anti-coagulants, which work by decreasing the clotting ability of the blood, to help stop blood clots from forming.

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.

DBL HEPARIN SODIUM INJECTION is used to:

- Prevent and treat blood clots in vessels that have started to clog up, in conditions such as deep vein thrombosis (DVT) and other blood vessel, heart and lung conditions.
- Prevent blood clots from forming during and/or surgery, kidney dialysis, blood transfusions or similar procedures, or if you have frostbite.

Your doctor may have prescribed it for another reason.

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

2. What should I know before being given DBL HEPARIN SODIUM INJECTION?

Warnings

Do not use DBL HEPARIN SODIUM INJECTION:

- If you have an allergy to heparin or medicines derived from heparin, pork products or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can be given this medicine.
- if you have, or have ever had, any of the following medical conditions: diseases or conditions where bleeding may be a problem, such as haemophilia, vitamin C deficiency, problems with fragile capillaries (small blood vessels), hiatus hernia, tumours, retinopathy (a disease of the eye), bleeding haemorrhoids (piles), stroke (bleeding on the brain), endocarditis (inflammation of the lining of the heart), very high blood pressure, low blood platelet count (thrombocytopenia), stomach or gut ulcers, or other conditions which may bleed, such as ulcerative colitis, severe kidney or liver disease, or very recent major surgery involving the eyes, brain or spinal cord.
- Tell your doctor if you are pregnant, and if so, whether you have a history of miscarriage, or if you have recently had a baby.
- If you have had problems with your blood after using pentosan polysulfate (a medicine used to treat cystitis).

Check with your doctor if you:

- have any other medical conditions such as: asthma or allergies, high blood pressure, ulcers, heart problems, cancer, diabetes, any disorders associated with your blood, have an infection, liver or kidney disease or eye diseases
- have had any very recent medical, surgical or dental procedures
- are scheduled to have any surgical or major dental procedures in the next few weeks
- are scheduled to have any contrast scans/x-rays in the next few weeks
- have any tummy/gut drainage tubes
- heavy or unusual menstrual periods.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or are breastfeeding.

When heparin is used in pregnant women, it may cause premature (early) delivery or harm your baby. Talk to your doctor about the risks and benefits of treatment with DBL HEPARIN SODIUM INJECTION in pregnancy and when breastfeeding.

Use in children

- DBL HEPARIN SODIUM INJECTION may be given to children.

Use in the elderly

- DBL HEPARIN SODIUM INJECTION should be used with caution in the elderly, especially in patients aged 60 years and above, as they may be at an increased risk of bleeding complications. Your doctor will consider this with treatment and will monitor accordingly.

3. What if I am taking other medicines?

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

Some medicines may interfere with DBL HEPARIN SODIUM INJECTION and affect how it works.

Medicines that may increase the effect of DBL HEPARIN SODIUM INJECTION (i.e. increase the risk of bleeding) include:

- medicines derived from heparin - such as dalteparin sodium or enoxaparin sodium
- other anticoagulants ('blood thinners') - such as warfarin
- non-steroidal anti-inflammatory drugs ('NSAIDs') - such as aspirin, naproxen, ibuprofen, diclofenac, piroxicam, meloxicam, indometacin and keterolac
- platelet inhibitors - such as clopidogrel, prasugrel, ticagrelor, tirofiban, eptifibatide and dipyradamole
- thrombolytics (clot-dissolving medicines) - such as alteplase, tenecteplase, apixaban, rivaroxaban and dabigatran
- dextran, a medicine used to treat 'shock', which occurs when you have dangerously low blood pressure
- systemic corticosteroids - for example prednisone, prednisolone, methylprednisolone, beclomethasone, dexamethasone, hydrocortisone and triamcinolone
- hydroxychloroquine, used to treat/prevent malaria, or to treat rheumatoid arthritis (RA) or systemic lupus erythematosus ('lupus')
- probenecid, used to treat gout
- medicines used to treat some cancers, known as 'cytostatics' - for example cytarabine, daunorubicin, fluorouracil and methotrexate
- asparaginase, used to treat a cancer of the white blood cells known as acute lymphocytic leukaemia ('ALL')
- some antibiotics - such as penicillin and cefamandole

- sodium valproate (also known as 'valproic acid'), used to treat epilepsy
- epoprostenol, used to treat pulmonary arterial hypertension ('PAH')
- propylthiouracil, used to treat thyroid issues
- contrast media used in some scans/x-rays

Medicines that may decrease the effect of DBL HEPARIN SODIUM (i.e. increase the risk of clotting) include:

- medicines to control bleeding such as andexanet alfa
- antihistamines (medicines used to prevent or relieve the symptoms of allergy, hay fever or rashes) - especially those containing diphenhydramine
- digoxin, a medicine used to treat heart failure
- tetracycline antibiotics, such as doxycycline, minocycline and tigecycline, used to treat some infections
- medicines that contain ascorbic acid (vitamin C)
- quinine, used to treat malaria
- glyceryl trinitrate (also known as nitroglycerin), used to treat angina (chest pain) and anal fissures
- nicotine (including e-cigarettes, vapes, nicotine patches, tablets etc.)
- alcohol

DBL HEPARIN SODIUM INJECTION may also increase blood potassium levels in patients taking the following medicines:

- potassium salts, some fluid tablets (e.g. amiloride, spironolactone and eplerenone), some medicines for heart problems (e.g. perindopril, lisinopril, enalapril and telmisartan, candesartan, irbesartan, losartan) and some antibiotics (e.g. trimethoprim and pentamidine).

DBL HEPARIN SODIUM may also increase the effects of:

- oral anti-diabetic drugs known as 'sulfonylureas', such as gliclazide, glimepiride and glipizide
- benzodiazepines, also known as 'benzos', such as diazepam, oxazepam, midazolam
- propranolol, used to treat high blood pressure and other heart issues.

If you are taking any of these medicines while using DBL HEPARIN SODIUM INJECTION, your doctor will need to carefully monitor your blood clotting factors and other blood levels, such as potassium.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL HEPARIN SODIUM INJECTION.

4. How is DBL HEPARIN SODIUM INJECTION given?

How much is given

Your doctor will decide what dose, how often and how long you will receive DBL HEPARIN SODIUM INJECTION.

How it is given

- DBL HEPARIN SODIUM INJECTION may be given as an injection under the skin (subcutaneously), by an injection into a vein, or through a slow infusion “drip” into a vein (intravenously). It should not be injected into muscle.

If you are given too much DBL HEPARIN SODIUM INJECTION

As DBL HEPARIN SODIUM INJECTION is being given to you in hospital, under the close supervision of your doctor, it is very unlikely that you will receive too much. Your condition will also be carefully monitored following administration.

Tell your doctor or nurse immediately if you are concerned that you may have been given too much DBL HEPARIN SODIUM INJECTION. Symptoms of an overdose may be abnormal bleeding from your bowel motion (poo), urine (wee), under your skin, from your nose, or abnormal bruising or coughing up blood.

5. What should I know during treatment with DBL HEPARIN SODIUM INJECTION?

Things you should do

Follow your doctor's instructions carefully and be sure to keep all medical appointments.

Tell your doctor if you notice any unusual bleeding, such as nose bleeds, bleeding gums after brushing your teeth, heavier than normal menstrual bleeding, excessive bleeding at the injection site, blood in your wee/poo, or from any open wounds or have unusual stomach pain.

Tell your doctor if you notice sudden or severe headaches, numbness or tingling, vision or hearing changes, memory loss, muscle weakness or tremors, balance and coordination issues, slurred or changed speech, seizures, unexplained fatigue, problems with swallowing, or changes in mood or personality.

Your doctor may ask you to have blood tests to check your progress and prevent unwanted side effects. If you are scheduled to have any blood tests or contrast scans/x-rays in the next few weeks after you leave hospital, remind your doctor that you have recently been given DBL HEPARIN SODIUM, as it may interfere with the results of some tests.

If you have any physical accidents once you leave hospital, seek medical attention and advise your treating doctor or nurse that you have been given DBL HEPARIN SODIUM recently, as you are at greater risk of bleeding and complications.

If you need medical, dental or surgical procedures in the next few weeks after you leave hospital, tell your doctor, dentist, anaesthetist or pharmacist that you have recently been treated with DBL HEPARIN SODIUM, as it may affect other medicines being used.

Remind any doctor, dentist or pharmacist that you visit that you have recently been treated with DBL HEPARIN SODIUM INJECTION.

Driving or using machines

Do not drive a car or use any machines or tools until you know how DBL HEPARIN SODIUM INJECTION affects you.

In some cases, DBL HEPARIN SODIUM INJECTION may cause drowsiness, tiredness, dizziness, confusion or anxiety/agitation.

Drinking alcohol

If you drink heavily, you have a greater risk of bleeding associated with DBL HEPARIN SODIUM INJECTION compared to moderate drinkers or non-drinkers.

Looking after your medicine

DBL HEPARIN SODIUM INJECTION will be stored in the pharmacy or on the ward under the correct conditions.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or nurse if you have any further questions about side effects.

If you are over 60 years of age you may have an increased chance of getting side effects, especially if you are female. Some side effects may occur several weeks after finishing treatment with DBL HEPARIN SODIUM INJECTION.

Side effects

Side effects	What to do
• Change in skin colour, or pain or bruising at the injection site, or small lumps under the skin • Hair loss • Increase in cholesterol • Receding gums, brittle nails, weaker hand grip, back pain, stooping posture (which could be early signs of osteoporosis)	Speak to your doctor or nurse if you have any of these side effects and they worry you.
• Allergic reaction (rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing) • Hypersensitivity reaction (fever and/or chills, runny nose, watering eyes, feeling sick or vomiting, headache, itchy soles of your feet) • Skin rash with dizziness, memory loss, confusion, cough, shortness of breath, severe tiredness, fever and mouth sores	If you are already in hospital, alert your doctor or nurse straight away, if you notice any of these side effects. If you have already left hospital, call

Side effects	What to do
• More intense pain/changes to skin colour 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, heavier than normal menstrual periods, bleeding from gums when brushing teeth) during or after treatment • Very low blood pressure ('shock'), which may cause you to feel pale, have cool or clammy skin, with a fast but weak heartbeat, rapid, shallow breathing, feeling sick or vomiting, blueish lips/fingernails, with dizziness, anxiety or agitation • Muscle weakness, numbness or tingling in the arms and legs, feeling sick or vomiting, especially with difficulty breathing, chest pain and a slow or irregular heartbeat • Blood in your wee or poo, black tarry poo, or vomiting blood • Severe back pain, weakness or numbness in your arms or legs, losing control of your bladder or bowel (wee or poo) • Pain in your tummy, back, side or groin, especially if tender, swollen or bruised, especially with fast heart rate and pale skin • Severe headache combined with feeling sick, vomiting, dizziness and confusion, or difficulty speaking or seeing, weakness or numbness on one side of your body • Dizziness, fatigue, muscle weakness, salt cravings, and potentially life-threatening heart palpitations or heart problems • Chest tightness or pain • Difficulty breathing • Collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech (signs of stroke) • A cough that may include bloody or blood-streaked mucus, rapid or irregular heartbeat, lightheadedness or dizziness, excessive sweating, fever, leg pain or swelling, or both, usually	your doctor, or go to the nearest hospital Emergency Department, if you notice any of these serious side effects

Side effects	What to do
• in the back of the lower leg, clammy or bluish-coloured skin • Changes in skin colour (red, purple, green, black), particularly on the hands and feet • Persistent, painful erection	

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side-effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or nurse before you decide to stop taking any of your medicines.

7. Product details

What DBL HEPARIN SODIUM INJECTION contains

Active ingredient (main ingredient)	heparin sodium (from pig intestines)
Other ingredients (inactive ingredients)	hydrochloric acid sodium hydroxide water for Injections

Do not take this medicine if you are allergic to any of these ingredients.

DBL HEPARIN SODIUM INJECTION does not contain lactose, sucrose, gluten, preservatives, tartrazine or any other azo dyes.

What DBL HEPARIN SODIUM INJECTION looks like

DBL HEPARIN SODIUM INJECTION is a clear, colourless or straw-coloured solution in glass ampoules.

5,000 IU / 1 mL: AUST R 12881

1,000 IU / 1 mL: AUST R 12883

5,000 IU / 0.2 mL: AUST R 16349

Who distributes DBL HEPARIN SODIUM INJECTION

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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