

DBL™ Vancomycin

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 healthcare professional.

1. Why am I being treated with DBL Vancomycin?

DBL Vancomycin contains the active ingredient vancomycin hydrochloride. DBL Vancomycin is used to treat severe bacterial infections. For more information, see Section [1. Why am I being treated with DBL Vancomycin?](#) in the full CMI.

2. What should I know before being treated with DBL Vancomycin?

Do not start treatment if you/your child have ever had an allergic reaction to vancomycin, other antibiotics that are the same type, or any of the ingredients listed at the end of the CMI. Your doctor will know which antibiotics are the same type.

Talk to your doctor if you/your child have had any allergic reaction to any antibiotic; have kidney or hearing problems, have inflammatory bowel disorders; take

any other medicines; or are pregnant, plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before being treated with DBL Vancomycin?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Vancomycin and affect how it works.

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

4. How is DBL Vancomycin given?

The doctor will decide how much DBL Vancomycin is needed. It will depend on factors such as the type of infection, age and bodyweight and if you/your child have kidney problems.

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

5. What should I know while being treated with DBL Vancomycin?

| Things you should do | |
|----------------------|---|
| | <ul style="list-style-type: none">• Tell your doctor if you/your child have kidney or hearing problems; have suffered from inflammatory bowel |

| | |
|--|--|
| | <p>disorders; had severe diarrhoea after taking any antibiotics; or if you are pregnant, plan to become pregnant or are breastfeeding.</p> <ul style="list-style-type: none"> • Tell your healthcare professional immediately if you develop a rash or any other sign of allergic reaction (shortness of breath, wheezing or difficulty breathing, swelling of the lips, face, throat, tongue or other parts of the body, rash, itching or hives on the skin) |
| <p>Things you should not do</p> | <p>You/your child should not be treated with DBL Vancomycin if you/your child have had an allergic reaction to vancomycin, the same type of antibiotics as DBL Vancomycin, or any of the other ingredients listed in Section 7. Product details. Your doctor will know which antibiotics</p> |

| | |
|------------------------------------|---|
| | are the same type as DBL Vancomycin. |
| Driving or using machines | Be careful before you drive a car or operate machinery until you know how Pfizer Vancomycin affects you. Vancomycin may cause dizziness in some people. |
| Looking after your medicine | Store in original carton at below 25°C until ready for use. |

For more information, see Section [5. What should I know while being treated with DBL Vancomycin?](#) in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include allergic reactions (chest pain, shortness of breath, wheezing or difficulty breathing, swelling of the lips, face, throat, tongue or other parts of the body, rash, itching or hives on the skin); rash or severe skin reaction that may be accompanied with a fever; severe stomach or abdominal cramps; nausea or vomiting, appetite loss, weight loss; fatigue, general aches and pains, pale skin; severe blisters and bleeding in the lips, eyes, mouth, nose or genitals; vertigo, dizziness, ringing in the ears or hearing loss; pain and irritation at the injection site; extremely tender, swelling and redness along a vein; fast, slow or irregular heartbeat, heart attack, drowsiness, loss

of consciousness, sweating, restlessness; upper body flushing, chest and backpain and muscle spasm; watery and severe diarrhoea which may also be bloody; fever, chills, other infections; bruising more than usual; kidney problems, little or no urine.

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™ Vancomycin

Active ingredient(s): vancomycin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Vancomycin. **You should also speak to your healthcare professional if you would like further information or if you have any concerns or questions about being given DBL Vancomycin.**

Where to find information in this leaflet:

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

1. Why am I being treated with DBL Vancomycin?

DBL Vancomycin contains the active ingredient vancomycin hydrochloride. DBL Vancomycin is a glycopeptide antibiotic use to treat severe bacterial infections.

2. What should I know before being treated with DBL Vancomycin?

Warnings

You/your child should not be given DBL Vancomycin if you/your child are:

- allergic to vancomycin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- allergic to or have previously had a severe allergic reaction to similar antibiotics as DBL Vancomycin. Your doctor will know which antibiotics are the same type as DBL Vancomycin.

Check with your doctor if you/your child:

- have kidney problems
- have hearing problems
- have inflammatory bowel disorders
- are taking any medicines for any other condition.

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

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with DBL Vancomycin and affect how it works.

These include:

- some other antibiotic medicines used to treat infections, such as aminoglycoside antibiotics (e.g. amikacin, gentamicin, neomycin and tobramycin), cephalosporin antibiotics (e.g. cefalexin, cefalotin, cefazolin, cefoxitin, cefuroxime, cefamandole, cefaclor, cefotaxime, ceftazidime, ceftriaxone, cefepime, ceftaroline fosamil, ceftolozane), colistin,

colistimethate sodium, capreomycin, piperacillin/tazobactam, clindamycin, ethambutol hydrochloride, and sulfadiazine

- amphotericin B, a medicine used to treat fungal infections
- medicine used to control and treat viral infections e.g. elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide, tenofovir alafenamide, adefovir dipivoxil, emtricitabine with tenofovir alafenamide, and cidofovir
- ciclosporin or tacrolimus, medicine used to suppress the immune system after organ transplants, severe rheumatoid arthritis, severe psoriasis, atopic dermatitis (skin allergies), and dry eye disease
- sulfasalazine, medicine used to treat inflammatory bowel diseases such as ulcerative colitis and Crohn's disease, and rheumatoid arthritis.
- some medicines used to treat pain and inflammation such as naproxen, ketorolac trometamol, flurbiprofen, and methoxyflurane
- etoricoxib, a medicine used to treat osteoarthritis, gout attacks, and relieve short-term pain
- medicines used to treat certain cancers, including cisplatin, carmustine, cyclophosphamide mitomycin, Mycobacterium bovis (Bacillus Calmette and Guerin (BCG) strain, and teicoplanin
- antithyroid medicines (e.g. propylthiouracil and carbimazole)
- clozapine, medicine used mainly in the treatment of schizophrenia
- fluid tablets (diuretics), such as furosemide (frusemide) and bumetanide

- anaesthetic agents, e.g. halothane, isoflurane, desflurane, sevoflurane, thiopental, fentanyl, alfentanil, ketamine, propofol, nitrous oxide, and esketamine
- colestyramine, a powder taken to lower cholesterol levels
- medicines used to relax muscles, such as suxamethonium, vecuronium, pancuronium, atracurium, cisatracurium, rocuronium bromide, mivacurium chloride, and botulinum toxin.

Check with your healthcare professional if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Vancomycin.

4. How is DBL Vancomycin given?

How much will be given

The doctor will decide what dose of DBL Vancomycin is needed depending on certain factors such as the type of infection, age, bodyweight, and if you/your child have kidney problems.

How long will DBL Vancomycin need to be given?

A course of treatment depends on the type, severity of the infection and how you/your child responds. The doctor will decide how many days you will need treatment with DBL Vancomycin.

How is DBL Vancomycin given?

DBL Vancomycin is given as either an injection into a vein or my mouth, depending on the infection. Vancomycin has an offensive taste.

If too much DBL Vancomycin is given

As DBL Vancomycin is generally given to you in hospital under the supervision of your healthcare professional, it is very unlikely that you will receive an overdose. Symptoms of a vancomycin overdose include the effects listed below in Section [6. Are there any side effects?](#), but are usually of a more severe nature.

If you think that you/your child have been given too much DBL Vancomycin, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being treated with DBL Vancomycin?

Things you should do

- Remind any doctors, nurses, dentists and pharmacists you see that you/your child are being given DBL Vancomycin.
- 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 soon after being given vancomycin, tell your doctor.

Tell your healthcare professional straight away if you/your child:

- get severe diarrhoea, severe abdominal or stomach cramps
- get a fever, in combination with one of all of the above.

Do this even if it occurs several weeks after DBL Vancomycin has been stopped.

Diarrhoea may be caused by a serious condition affecting the bowel. You or your child may need urgent medical care.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Pfizer Vancomycin affects you.

Pfizer Vancomycin may cause dizziness in some people.

Looking after your medicine

DBL Vancomycin will be stored in the pharmacy or on the ward. The injection is kept in a cool, dry place away from moisture, heat or sunlight, where the temperature stays below 25°C. The expiry date will be checked that it has not passed.

6. Are there any side effects?

All medicines can have side effects. If you/your child 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 healthcare professional if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">● irritation at the injection site● nausea, vomiting or mild diarrhoea● dizziness● redness and flushing in children. | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none">● severe pain, warmth, itching, redness of the skin at the injection site● severe blisters and bleeding in the lips, eyes, mouth, nose or genitals● severe flaking or peeling of the skin● fluid-filled blisters that are located along creases in the skin which may be itchy | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects. |

| Serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● severe skin reaction starting with painful red areas, then large blisters and end with peeling layers of skin, accompanied by fever and chills, aching muscles and generally feeling unwell ● rash with small puss-filled blisters that may be accompanied by a fever ● pain, swelling and redness along a vein which is extremely tender when touched ● itchy spots accompanied by fever and feeling unwell ● signs of an allergic reaction, such as chest pain, shortness of breath, wheezing, coughing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin ● bleeding or bruising more easily than normal | |

| Serious side effects | What to do |
|--|-------------------|
| <ul style="list-style-type: none"> ● flushing of the upper body or pain and muscle spasm of the chest and back ● chills or fever, which may be accompanied by shivering ● fever, loss of appetite, weight loss, fatigue, general aches and pains ● severe and constant abdominal pain, fever, inability to break wind or pass stools, nausea and vomiting, shock ● fast, slow or irregular heart beat, heart palpitations ● dizziness and lightheadedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness; heart attack ● ringing in the ears (tinnitus) or hearing loss, deafness, dizziness or problems with your balance | |

| Serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● diarrhoea, usually with blood and mucus, stomach pain, fever ● frequent infections such as fever, severe chills, sore throat or mouth ulcers; tiredness, being short of breath and looking pale ● little or no urine, drowsiness, nausea, vomiting, breathlessness, kidney disease ● other infections. | |

Tell your healthcare professional 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/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

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

What DBL Vancomycin contains

| | |
|---|---|
| Active ingredient (main ingredient) | Vancomycin hydrochloride |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">• disodium edetate• hydrochloric acid• sodium hydroxide |

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

What DBL Vancomycin looks like

DBL Vancomycin is a white to off-white powder, which will be dissolved to a clear solution before it is given to you.

DBL Vancomycin is available in the following strengths and pack sizes:

- Vials containing 500 mg (500,000 IU) of vancomycin activity; packs of 1 and 10 vials (AUST R 62603)
- Vials containing 1000 mg (1,000,000 IU) of vancomycin activity, packs of 1 vial, (AUST R 62595).

Who distributes DBL Vancomycin

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

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