DBL ™ Tobramycin 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 pharmacist.

1. Why am I being treated with DBL Tobramycin Injection BP ?

DBL Tobramycin Injection BP contains the active ingredient tobramycin. DBL Tobramycin Injection BP is used for the treatment of serious infections caused by bacteria. For more information, see Section 1. Why am I being given DBL Tobramycin Injection BP? in the full CMI.

2. What should I know before being treated with DBL Tobramycin Injection BP?

Do not use if you have ever had an allergic reaction to tobramycin or any similar medicines, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions including kidney problems, muscular disorders, cystic fibrosis, hearing problems or mitochondrial disorders; take any other medicines; are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before being given DBL Tobramycin Injection BP? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Tobramycin Injection BP 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 Tobramycin Injection BP given?

- Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and kidney function.
- DBL Tobramycin Injection BP is given as an injection into a muscle or as a slow injection (drip) into a vein (intravenously) and should only be given by a doctor or nurse.

More instructions can be found in Section 4. How is DBL Tobramycin Injection BP given? in the full CMI.

5. What should I know during treatment with DBL Tobramycin Injection BP?

Things you should do	• Remind any doctor, nurse, dentist or pharmacist you visit that you are given DBL Tobramycin injection BP. • If you are going to have surgery tell the surgeon or anaesthetist that you are being given this medicine. • If you become pregnant while being treated with tobramycin, tell your doctor immediately.
Driving or using machines	• Be careful driving or operating machinery until you know how DBL Tobramycin Injection BP affects you.
Drinking alcohol	• No information is available.

For more information, see Section 5. What should I know during treatment with DBL Tobramycin Injection BP? in the full CMI.

6. Are there any side effects?

Tiredness,weakness;tingling,numbness,pins and needles or pain in the hands or feet;dizziness;headache;fever;nausea, vomiting; sore mouth and gums;pain at the injection site;rash or itching;signs of anaemia (tiredness, being short of breath, looking pale); mental confusion,disorientation. Serious side effects may include signs of an 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 difficulty breathing or swallowing); severe flaking or peeling of the skin;severe skin reaction with painful red areas,large blisters and peeling of layers of skin accompanied by fever and chills,aching muscles and generally feeling unwell;severe blisters and bleeding in the lips, eyes, mouth, nose and genitals; hearing problems such as hearing loss,ringing or unusual sounds in the ears;vertigo;roaring in the ears even after stopping treatment for several weeks;double vision;drooping eyelids,difficulty in speaking and swallowing, muscle weakness in the arms or legs;muscle cramps;increased or decreased urination;diarrhoea even several weeks after stopping treatment; bleeding or bruising more easily than normal.

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™ Tobramycin Injection BP (toh-bruh-mahy-sin)

Active ingredient(s): *tobramycin*

Consumer Medicine Information (CMI)

This leaflet provides important information about being treated with DBL Tobramycin Injection BP. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being treated with DBL Tobramycin Injection BP.**

Where to find information in this leaflet:

1. Why am I being treated with DBL Tobramycin Injection BP ?
2. What should I know before being treated with DBL Tobramycin Injection BP?
3. What if I am taking other medicines?
4. How is DBL Tobramycin Injection BP given?
5. What should I know during treatment with DBL Tobramycin Injection BP?
6. Are there any side effects?
7. Product details

1. Why am I being treated with DBL Tobramycin Injection BP?

DBL Tobramycin Injection BP contains the active ingredient tobramycin. DBL Tobramycin Injection BP is an antibiotic that belongs to a group of medicines called aminoglycosides. Tobramycin works by preventing bacteria from growing and thereby killing them.

DBL Tobramycin Injection BP is used to treat serious infections caused by bacteria including;

- meningitis (infection of the brain)
- septicaemia (infection of the blood)
- neonatal sepsis (infection in infants)
- lower respiratory tract infections
- gastrointestinal tract infections
- bone, skin and skin structure infections, including burns
- urinary tract infections

2. What should I know before being treated with DBL Tobramycin Injection BP?

Warnings

DBL Tobramycin Injection BP should not be given to you if you are allergic to:

- tobramycin, or any of the ingredients listed at the end of this leaflet
- any similar medicines such as amikacin, neomycin, gentamicin, vancomycin, colistin, cisplatin or neomycin
- sulfites

Always check the ingredients to make sure you can use this medicine.

Before you are given it, tell your doctor or pharmacist if you have allergies to:

- any other medicines
- sulfites
- food preservatives or dyes.

Tell your doctor or nurse if you have or have had any medical conditions, especially the following:

- kidney disease or kidney problems
- muscular disorders (e.g. myasthenia gravis, Parkinson's disease)
- cystic fibrosis
- hearing problems, or if you or your family have a mitochondrial mutation disease, or loss of hearing due to antibiotic medicines; certain mitochondrial mutations may increase your risk of hearing loss with this product.

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

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.

DBL Tobramycin Injection BP is potentially harmful to the fetus.

Your doctor will discuss with you the benefits and risks of using it during pregnancy and breastfeeding.

DBL Tobramycin Injection BP is potentially harmful to your baby.

3. What if I am taking other medicines?

Tell your doctor, nurse or pharmacist 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 Tobramycin Injection BP and affect how it works.

These medicines may be affected by tobramycin or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use different medicines. Your doctor, nurse or pharmacist will advise you.

Your doctor, nurse and pharmacist may have more information on medicines to be careful with or avoid while receiving tobramycin. e.g.

- fluid tablets (diuretics) e.g. furosemide (frusemide), etacrynic acid
- cisplatin, a medicine used to treat cancer
- ciclosporins, a medicine used to stop organ rejection in transplant patients
- other antibiotics to treat infections, including penicillins, cephalosporins, particularly cefalotin, and aminoglycosides vancomycin, amikacin, gentamicin, as well as colistin and neomycin
- amphotericin B, an antifungal medicine
- opioid pain medicines (e.g. codeine, morphine, pethidine, fentanyl)
- methoxyflurane an inhaled medicine for strong pain relief
- skeletal muscle relaxants, such as suxamethonium
- medicines used to prevent blood clots, e.g. warfarin, phenindione
- neostigmine and pyridostigmine, medicines used to treat myasthenia gravis.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Tobramycin Injection BP.

4. How is DBL Tobramycin Injection BP given?

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and kidney function.

How is DBL Tobramycin Injection BP given

- DBL Tobramycin Injection BP is given as an injection into a muscle or as a slow injection (drip) into a vein (intravenously) and should only be given by a doctor or nurse.

If you are given too much DBL Tobramycin Injection BP

As DBL Tobramycin Injection BP is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

However, if you experience any dizziness, ringing or unusual sounds in the ears, vertigo or change in hearing, or severe side effects tell your doctor or nurse immediately or if you are not already in hospital, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at the nearest hospital.

You may need urgent medical attention.

Symptoms of a tobramycin overdose may include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

5. What should I know during treatment with DBL Tobramycin Injection BP?

Things your doctor should do

Your doctor should monitor blood and urine test results regularly while you are receiving DBL Tobramycin Injection BP. This is to ensure that you are receiving the correct dose of tobramycin.

Things you should do

If you are about to be started on any new medicine, remind your doctor, nurse, dentist or pharmacist that you are being given DBL Tobramycin Injection BP.

Tell any other doctors, nurses, dentists, and pharmacists who are treating you that you are being given DBL Tobramycin Injection BP.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given DBL Tobramycin Injection BP.

It may affect other medicines used during surgery.

If you become pregnant while being treated with DBL Tobramycin Injection BP, tell your doctor immediately.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Tobramycin Injection BP affects you.

DBL Tobramycin Injection BP may cause tiredness, dizziness, or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous. Children should be careful performing activities requiring attention such as riding bicycles or climbing.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Drinking alcohol

No information is available.

Looking after your medicine

DBL Tobramycin Injection BP is stored in the pharmacy or on the hospital ward.

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 pharmacist if you have any further questions about side effects. If you have myasthenia gravis, are dehydrated, or over 65 years of age you may have an increased chance of getting side effects.

Side effects	What to do
• tiredness or weakness • tingling, numbness or pain of the hand or feet, or pins and needles • dizziness or headache • fever • nausea or vomiting • sore mouth and gums • pain at the injection site • rash or itching • signs of anaemia, such as tiredness, being short of breath and looking pale • mental confusion and disorientation	**Speak to your doctor or nurse if you have any of these side effects and they worry you.**

Serious side effects	What to do
• signs of an allergic reaction such as; rash, itching, hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing or swallowing • severe flaking or peeling of the skin • severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin which is accompanied by fever and chills, aching muscles and generally feeling unwell • rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals • hearing problems such as hearing loss, ringing or unusual sounds in the ears (tinnitus), vertigo, roaring in the ears even after stopping treatment for several weeks. • double vision • drooping eyelids • difficulty in speaking and swallowing, muscle weakness in the arms or legs, muscle cramps • difficulty breathing • increased or decreased urination • diarrhoea, even after stopping treatment for several weeks • bleeding or bruising more easily than normal	**Tell your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist 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 pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DBL Tobramycin Injection BP contains

Active ingredient (main ingredient)	tobramycin
Other ingredients (inactive ingredients)	sodium metabisulfite disodium edetate sulfuric acid sodium hydroxide Water for injections

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

What DBL Tobramycin Injection BP looks like

DBL Tobramycin Injection BP is a clear, colourless liquid in vials.

80 mg/2 mL (AUST R 75686).

Who distributes DBL Tobramycin Injection BP

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229
www.pfizermedicalinformation.com.au

This leaflet was prepared in October 2025.