

DBL™ Tobramycin Injection BP

Tobramycin (toe-bra-MYE-sin)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Tobramycin 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 DBL™ Tobramycin Injection BP 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 in a safe place. You may need to read it again.

What DBL™ Tobramycin Injection BP is used for

Tobramycin is an antibiotic that belongs to a group of medicines called aminoglycosides (pronounced a-my-noe-GLY-koesides).

Tobramycin works by preventing bacteria from growing and thereby killing them. Tobramycin is used for the treatment of serious infections caused by bacteria, including:

- meningitis (infection of the brain)
- septicaemia (infection of the blood)
- respiratory tract infections
- gastrointestinal tract infections

- skin and skin structure infections, including infected burns
- bone infections
- urinary tract infections.

Your doctor may have prescribed tobramycin for another reason.

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

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

Before you are given DBL™ Tobramycin Injection BP

When you must not be given it

You must not be given DBL™ Tobramycin Injection BP if you have an allergy to tobramycin or any of the ingredients listed at the end of this leaflet.

You must not be given tobramycin if you have an allergy to any other aminoglycoside antibiotics such as:

- amikacin
- gentamicin
- neomycin.

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 must not be given tobramycin if you have experienced serious reactions (such as hearing loss or kidney problems) to tobramycin or other aminoglycosides, such as amikacin, gentamicin, or neomycin, in the past.

If you are not sure whether you should be given tobramycin, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most aminoglycoside antibiotics, tobramycin is not recommended for use during pregnancy. If there is a need for you to be given tobramycin, your doctor will discuss with you the benefits and risks of using it during your pregnancy.

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

Tobramycin passes into breast milk and is not recommended for use during breast-feeding. If there is a need for you to be given tobramycin, your doctor will discuss the possible risks and benefits of using it during breast-feeding.

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

- kidney problems
- muscular disorders (eg myasthenia gravis, Parkinson's disease)

- hearing problems.

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

Taking other medicines

Tell your doctor or pharmacist 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 tobramycin may interfere with each other. These include:

- fluid tablets (diuretics) eg frusemide, ethacrynic acid, bumetanide
- cisplatin, a medicine used to treat cancer
- other antibiotics to treat infections such as colistin, vancomycin, cephalosporins and penicillins
- amphotericin, an antifungal medicine
- opioid analgesics (eg codeine, morphine, pethidine, fentanyl)
- some general anaesthetic agents
- muscle relaxants (eg succinylcholine).

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 or pharmacist will advise you.

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

How DBL™ Tobramycin Injection BP is 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 it is given

Tobramycin is given as an injection into a muscle or as a slow injection into a vein (intravenously).

Tobramycin should only be given by a doctor or nurse.

If you take too much (overdose)

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 severe side effects tell your doctor or nurse immediately or if you are not already in hospital, go to the Accident & Emergency Department at your nearest hospital.

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.

In case of overdose, immediately contact the Poisons Information Centre for advice. (In Australia, call 13 11 26; in New Zealand call 0800 764 766.)

While you are being given DBL™ Tobramycin Injection BP

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given tobramycin.

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given tobramycin.

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

Things to be careful of

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

As with other aminoglycoside medicines, tobramycin may cause feelings of tiredness or drowsiness in some people. Make sure you know how you react to tobramycin before you drive a car, operate machinery, or do anything else that could be dangerous if you are tired or drowsy. If this occurs do not drive.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being treated with tobramycin.

Tobramycin helps most people with certain infections, 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 treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

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

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

- tiredness or weakness
- fever
- nausea or vomiting
- sore mouth and gums
- pain at the injection site.

These side effects are usually mild.

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

- signs of an allergic reaction, such as 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
- hearing problems
- ringing in the ears
- muscle weakness
- decreased urination.

These are very serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may occur in some patients.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using DBL™ Tobramycin Injection BP

Storage

DBL™ Tobramycin 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™ Tobramycin Injection BP is a clear, colourless liquid and comes in glass vials.

Ingredients

Active ingredient:

- tobramycin.

Other ingredients:

- disodium edetate
- sodium metabisulfite
- sulfuric acid.

DBL™ Tobramycin Injection BP does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Australian Sponsor:
Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
23 Haining Street
Te Aro
Wellington
New Zealand

DBL™ Tobramycin Injection BP is available in the following strength and pack size:

- Tobramycin 80 mg/2 mL x 5 vials. (AUST R 75686)

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