

TOBRAMYCIN INJECTION

tobramycin sulfate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tobramycin Injection.

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 taking Tobramycin Injection against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What Tobramycin Injection is used for

Tobramycin Injection belongs to a group of medicines known as aminoglycoside antibiotics.

Aminoglycoside antibiotics work by preventing bacteria from growing, thereby killing them.

Tobramycin Injection is used to treat serious bacterial infections in many different parts of the body such as:

- meningitis (infection of the brain)
- septicaemia (infection of the blood)
- respiratory tract infections (such as pneumonia, bronchitis)
- gastrointestinal tract infections

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

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

Your doctor may have prescribed it for another reason.

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

Before you are given Tobramycin Injection

When you must not be given it

You must not be given Tobramycin Injection if you have an allergy to:

- any medicine containing tobramycin
- any other similar medicines such as aminoglycoside antibiotics e.g. gentamicin, streptomycin, amikacin or neomycin
- any of the ingredients listed at the end of this leaflet
- sulfites.

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 Injection if you have experienced serious reactions (such as hearing loss or kidney problems) to tobramycin or other

aminoglycosides such as amikacin, streptomycin, gentamicin, or neomycin in the past.

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
- sulfites
- 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 breastfeeding. If there is a need for you to be given tobramycin, your doctor will discuss with you the benefits and risks of being given Tobramycin Injection whilst you are breast-feeding.

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

- kidney disease or any kidney problems
- 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

- muscular disorders (e.g. myasthenia gravis, Parkinson's disease)
- cystic fibrosis.

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 if you are taking any other medicines, including any that you get 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) such as furosemide (frusemide), etacrynic acid, bumetanide
- cisplatin, a medicine used to treat cancer
- other antibiotics to treat infections, including ciclosporins and cephalosporins, particularly cefalotin
- amphotericin, an antifungal medicine
- opioid analgesics (e.g. codeine, morphine, pethidine, fentanyl)
- some general anaesthetic agents
- muscle relaxants such as suxamethonium
- some medicines used to prevent blood clots, e.g. warfarin, phenindione
- any drug that may cause kidney or hearing problems
- neostigmine and pyridostigmine, medicines used to treat myasthenia gravis.

These medicines may be affected by tobramycin or may affect how well it works. You may need different amounts of your medicines, or you may need to take a different medicine.

Your doctor has more information on medicines to be careful with or avoid while you are receiving Tobramycin Injection.

How Tobramycin Injection is given

How much is given

Your doctor will decide how much Tobramycin Injection you will be given and for how long. This depends on the type of infection and other factors, such as your weight and your kidney function.

How it is given

Tobramycin Injection must only be given by a doctor or nurse.

Tobramycin Injection can be given:

- directly into a vein via an injection (intravenously), which is infused over a period of 20 to 60 minutes (Tobramycin Injection will be diluted before being injected into your vein)
- as a deep injection into a large muscle (intramuscular).

If you are given too much (overdose)

As Tobramycin Injection 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, 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.

While you are being given Tobramycin Injection

Things your doctor should do

Your doctor or nurse should take regular blood and urine samples while you are receiving Tobramycin Injection. This is to ensure that you are receiving the correct dose of tobramycin.

Things you must do

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist who treats you that you are being given this medicine.

Tell any other doctors, dentists and pharmacists who are treating 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 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 Injection affects you.

This medicine 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.

Side effects

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

This medicine 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 attention if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of side effects.

If you are dehydrated you may have an increased chance of getting side effects.

Do not be alarmed by the following list of possible side effects.

You may not experience any of them.

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

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

- tiredness or weakness
- dizziness or headache
- fever
- nausea or vomiting
- sore mouth and gums
- pain, swelling or red skin where you had the injection
- rash or itching
- signs of anaemia, such as tiredness, being short of breath and looking pale
- confusion or disorientation.

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 lips, face, tongue, or other parts of the body; shortness of breath, wheezing or difficulty breathing
- hearing problems
- ringing in the ears (tinnitus)
- vertigo
- muscle weakness
- increase or decrease in urination
- diarrhoea, even after stopping antibiotics for several weeks
- bleeding or bruising more easily than normal.

The above list includes very serious side effects that may require urgent medical attention.

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

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

After you have been given Tobramycin Injection

Storage

Tobramycin Injection will be stored in the pharmacy or on the ward. It is kept where the temperature stays below 30°C and protected from light.

Product Description

What it looks like

Tobramycin Injection is a clear, colourless to pale brown, sterile aqueous solution in a plastic ampoule.

Ingredients

Active ingredient:

- tobramycin (as tobramycin sulfate) 80 mg/2 mL

Other ingredients:

- disodium edetate
- phenol
- sulfuric acid
- sodium hydroxide
- sodium metabisulfite
- Water for Injections.

Supplier

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free Number: 1800 675 229
www.pfizermedinfo.com.au

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

- Tobramycin 80 mg/2 mL (as tobramycin sulfate) x 5 ampoules (AUST R 101217).

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