

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

Do not use Tobramycin Injection if you have an allergy to:

- any medicine containing tobramycin
- any of the ingredients listed at the end of this leaflet
- any other similar medicines such as aminoglycoside antibiotics e.g. gentamicin, streptomycin, amikacin or 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 Injection if you have experienced serious reactions (such as hearing loss or kidney problems) to tobramycin or other aminoglycosides 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, 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
- myasthenia gravis (a muscle disease)
- Parkinson's disease (a disease affecting movement)

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:

- antibiotics
- fluid tablets (diuretics) such as furosemide (frusemide), etacrynic acid, bumetanide
- anticancer drugs such as cisplatin
- any drug that may cause kidney or hearing problems
- amphotericin, an anti-fungal medicine
- muscle relaxants such as suxamethonium

These medicines be may affected by tobramycin or may be 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 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).

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.

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 are given too much tobramycin you may experience some of the effects listed under "Side effects" below.

Your doctor has information on how to recognise and treat an overdose.

Ask your doctor if you have any concerns.

If you experience severe side effects, tell your doctor immediately or go to the nearest hospital emergency department.

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 or pharmacist who treats you that you are taking this medicine.

Tell all doctors and dentists and pharmacists who are treating you that you are being given tobramycin.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking 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 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.

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.

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.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

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

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

- pain, swelling or red skin where you had the injection
- fever
- skin problems such as rash or itching
- headache

- signs of anaemia, such as tiredness, being short of breath and looking pale
- bruising more easily than normal
- confused state
- disorientation
- nausea
- vomiting.

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

- swelling of the lips, face, mouth, throat or limbs; breathing difficulty, or shortness of breath; rash, itching, hives
- kidney problems, e.g. increase or decrease in urination
- dizziness
- ringing in the ears (known as tinnitus)
- hearing loss
- vertigo
- muscle weakness
- diarrhoea, even after stopping antibiotics for several weeks.

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 received Tobramycin Injection

Storage

Tobramycin Injection will be stored in the pharmacy or 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 40% v/v
- sodium hydroxide
- sodium metabisulfite
- Water for Injections.

Supplier

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.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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