

TOBRAMYCIN INJECTION

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 nurse.

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.

This medicine is likely to be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given to you after the medicine has been used.

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

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

Tobramycin Injection may be prescribed for other reasons that are not mentioned above. Your doctor will be able to tell you about the specific condition for which you have been prescribed it.

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

Before you are given Tobramycin Injection

Do not use Tobramycin Injection if:

- you have an allergy to tobramycin or any of the ingredients listed at the end of this leaflet
- you have an allergy to other aminoglycoside antibiotics such as 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 any of these apply to you, check with your doctor.

Before you are given it

Tell your doctor if:

1. you have any allergies to:

- any other medicine
- any other substances, such as foods, preservatives or dyes

2. you are pregnant or intend to become pregnant

Tobramycin may affect your developing baby if you take it during pregnancy. If it is necessary for you to be given Tobramycin Injection, your doctor will discuss with you the benefits and risks of using it during pregnancy.

3. you are breastfeeding or plan to breastfeed

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 breastfeeding.

4. 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 buy 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 frusemide, ethacrynic 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 may affect the way tobramycin works or may be affected by tobramycin. You may need different amounts of your medicine, or you may need to take a different medicine.

Your doctor will advise you about continuing to take other medicines 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

Tell all doctors and dentists who are treating you that you are using tobramycin.

While you are using tobramycin, tell your doctor, nurse or pharmacist before you start any new medicine.

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

Things to be careful of

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 given or using tobramycin.

Like other medicines, tobramycin may cause some unwanted side effects. These are likely to vary from patient to patient. Some side effects may be related to the dose of tobramycin. Hence, it is important that you tell your doctor as soon as possible about any unwanted effects. Your doctor may then decide to adjust the dose of tobramycin you are given.

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

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

If any of the following happen tell your doctor or nurse immediately or if you are not already in hospital, go to the emergency department at your nearest hospital:

- swelling of the lips, face, mouth, throat or limbs
- breathing difficulty, or shortness of breath
- rash, itching, hives

These may be symptoms of an allergic reaction to tobramycin.

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

- kidney problems, e.g. increase or decrease in urination
- dizziness
- ringing in the ears (known as tinnitus)
- hearing loss
- vertigo

These are serious side effects of Tobramycin Injection. You may need urgent medical attention.

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
- diarrhoea

After you have received Tobramycin Injection

Tell your doctor or nurse immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with Tobramycin Injection:

- kidney problems, e.g. increase or decrease in urination
- dizziness
- ringing in the ears (known as tinnitus)
- hearing loss
- vertigo

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor. Some side effects may only be seen by your doctor.

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.

Tobramycin Injection can be identified by an Australian Registration Number, which is found on the packaging: AUST R 101217.

Ingredients

Tobramycin Injection contains tobramycin (as Tobramycin Sulfate BP) 80mg/2mL, Disodium Edetate BP, Phenol BP, 40% v/v Sulfuric Acid and Sodium Metabisulfite BP in Water for Injections BP.

Manufacturer

Pfizer (Perth) Pty Limited
ABN 32 051 824 956
15 Brodie Hall Drive,
Bentley WA 6102 Australia

Sponsor in Australia

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114 Australia

This Consumer Medicine Information was written in 24 April 2004.

Date of most recent amendment: 11 February 2011.