

Tobramycin Mylan

tobramycin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tobramycin Mylan.

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 Mylan against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Tobramycin Mylan is used for

This medicine is used to treat serious bacterial infections.

- 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.

It belongs to a group of medicines called aminoglycoside antibiotics.

This medicine works by preventing bacteria from growing and thereby killing them.

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 Mylan

When you must not be given it

You must not be given Tobramycin Mylan 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 amikacin, gentamycin and neomycin

Some of the 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 a history of hypersensitivity or serious toxic reactions tobramycin or any other aminoglycosides.

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 have or have had any of the following medical conditions:

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

Tell your doctor if you are pregnant or plan 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 in to 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.

If you have not told your doctor about any of the above, tell him/her before you are given Tobramycin Mylan.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Tobramycin Mylan may interfere with each other. These include:

- ethacrynic acid, frusemide, bumetanide or other potent diuretics.
- neurotoxic or nephrotoxic antibiotics such as aminoglycosides, cephaloridine, polymixin B, colistin, cisplatin and vancomycin.
- amphotericin, a medicine used to treat fungal infections.
- Opioid analgesics (eg codeine, morphine, pethidine, fentanyl)
- Some general anaesthetic agents
- muscle relaxants (eg succinylcholine)

These medicines may be affected by Tobramycin Mylan or may affect how well it works. You may need different amounts of your medicines, or you may need to be given different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How Tobramycin Mylan is given

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

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 telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Tobramycin Mylan.

You may need urgent medical attention.

While you are being given Tobramycin Mylan

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tobramycin Mylan.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

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 taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests (urine tests and serum tests) from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

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

This medicine may cause (dizziness, light-headedness, tiredness, drowsiness, etc.) in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Tobramycin Mylan.

This medicine helps most people with certain infections, but it may have unwanted side effects in some 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.

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

You may not experience any of them.

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

Tell your doctor or pharmacist 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.

The above list includes the more common side effects of your

medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare

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.

- sulfuric acid
- sodium hydroxide

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Tobramycin Mylan is supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000

Phone: (02) 9298 3999

www.mylan.com.au

Australian registration numbers:

Tobramycin Mylan 80 mg/2 mL:

AUST R 234429

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After using Tobramycin Mylan

Storage

Tobramycin Mylan 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

Tobramycin Mylan is a clear, colorless liquid filled in a glass vial.

Ingredients

Tobramycin Mylan contains tobramycin as the active ingredient.

It also contains the following inactive ingredients:

- disodium edetate
- sodium bisulfite