

NEW ZEALAND CONSUMER MEDICINE INFORMATION

TOBRAMYCIN MYLAN

Tobramycin, solution for injection, 80 mg/2 mL



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 risks and benefits. Your doctor has weighed the risks of you using Tobramycin Mylan against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Tobramycin Mylan is used for

Tobramycin Mylan is used to treat:

- meningitis (infection of the brain)
- septicaemia (infection of the blood)
- respiratory tract infections
- gastrointestinal tract infections
- skin, bone and skin structure infections, including burns
- urinary tract infections.

Tobramycin Mylan contains the active ingredient tobramycin. It belongs to a group of medicines called aminoglycoside antibiotics.

It 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

Do not use 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 aminoglycoside antibiotics such as amikacin, streptomycin, neomycin, kanamycin, gentamicin and paromomycin.

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 experienced serious reactions (such as hearing loss or kidney problems) to tobramycin or other aminoglycosides, such as, gentamicin or neomycin, in the past.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you start to use 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 (e.g. myasthenia gravis, Parkinson's disease)
- hearing problems.

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

Tobramycin is not recommended for use during pregnancy or in breast-feeding. If there is a need for you to be given tobramycin, your doctor can discuss with you the risks and benefits involved.

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 your pharmacy, supermarket or health food shop.

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

- fluid tablets (diuretics), such as ethacrynic acid and furosemide
- neurotoxic or nephrotoxic antibiotics such as aminoglycosides, cephaloridine, viomycin, polymyxin B, colistin, cisplatin and vancomycin

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 take 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

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.

Tobramycin should only be given by a doctor or nurse.

How long to use it

Your doctor will decide the length of time that you will receive tobramycin depending on your condition. Use the medicine for as long as the doctor recommends.

If you are given 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 an overdose, immediately tell your doctor or nurse or telephone the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, if you think that you may have been given too much Tobramycin Mylan. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using 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 using Tobramycin Mylan.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are using 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 from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not use Tobramycin Mylan to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor.

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 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.

Do not be alarmed by the following lists 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 nurse if you notice any of the following and they worry you:

- tiredness or weakness
- fever
- nausea or vomiting
- diarrhoea
- headache
- pain at the injection site
- confusion.

These side effects are usually mild and short-lived.

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.

The above list includes very serious side effects. You may need urgent medical attention. Serious 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.

After using Tobramycin Mylan

Storage

Tobramycin Mylan will be stored in the pharmacy or in the hospital 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, colourless liquid filled in a glass vial.

Ingredients

Tobramycin Mylan contains tobramycin as the active ingredient.

It also contains:

- disodium edetate
- sodium bisulfite
- sodium hydroxide
- sulphuric acid

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

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of Information

20 July 2018
(Based on datasheet dated 20 July 2018)