

TOBRAMYCIN VIATRIS

Tobramycin, solution for injection, 80 mg/2 mL



What is in this leaflet

Please read this leaflet carefully before you start using Tobramycin Viatriis.

This leaflet answers some common questions about Tobramycin Viatriis.

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 Viatriis 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 Viatriis is used for

Tobramycin Viatriis 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 Viatriis 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. Your doctor may have prescribed this medicine for another reason.

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

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

Before you are given Tobramycin Viatriis

When you must not be given it

Do not use Tobramycin Viatriis 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.

Tobramycin Viatriis should only be given as an injection into the muscle or as a slow injection into the veins.

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 start using 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)
- cystic fibrosis
- hearing problems.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Tobramycin is not recommended for use during pregnancy or in breastfeeding. 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 them before you start using Tobramycin Viatriis.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are using Tobramycin Viatriis.

Some medicines may interfere with Tobramycin Viatriis. These include:

- fluid tablets (diuretics), such as ethacrynic acid and furosemide
- neurotoxic or nephrotoxic antibiotics such as neomycin, streptomycin, kanamycin, gentamicin, paromomycin, viomycin, amikacin, cefaloridine,

- polymyxin B, colistin, cisplatin and vancomycin
- other antibiotics including ciclosporins and cephalosporins, particularly cefalotin
- some general anaesthetics or opioid analgesics
- muscle relaxants such as suxamethonium
- medicines used to prevent blood clots such as warfarin and phenindione
- neostigmine and pyridostigmine, medicines used to treat myasthenia gravis
- amphotericin, an antifungal medicine.

These medicines may be affected by Tobramycin Viatris 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 using this medicine.

How to Tobramycin Viatris 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.

While you are using Tobramycin Viatris

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Tobramycin Viatris.

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 using this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are using 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 Viatris 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.

Things to be careful of

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

In case of overdose

If you are given too much (overdose)

As Tobramycin Viatris 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 Viatris. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

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

- sore mouth and gums
- pain at the injection site
- rash or itching
- signs of anaemia, such as tiredness, being short of breath and looking pale
- confusion and disorientation.

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
- diarrhoea, even after stopping antibiotics for several weeks
- bleeding or bruising more easily than normal.

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 Viatris

Storage

Tobramycin Viatris 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 Viatris is a clear, colourless liquid filled in a glass vial.

Ingredients

Active ingredient(s):

Tobramycin Viatris contains tobramycin as the active ingredient.

Inactive ingredient(s):

Tobramycin Viatris also contains:

- disodium edetate
- sodium bisulfite
- sodium hydroxide
- sulfuric acid

If you want to know more

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

Who supplies this medicine

Tobramycin Viatris is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

17 September 2024
(Based on datasheet dated 17 September 2024)