

TOBRAMYCIN VIATRIS

tobramycin

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about TOBRAMYCIN VIATRIS.

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 VIATRIS 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 VIATRIS is used for

Tobramycin is an antibiotic that belongs to a group of medicines called aminoglycoside antibiotics.

Tobramycin works by preventing bacteria from growing and thereby killing them. Tobramycin is used to treat serious bacterial infections, including:

- 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.

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 VIATRIS

When you must not be given it

You must not be given TOBRAMYCIN VIATRIS if you have an allergy to:

- sulfites
- 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 (such as hearing loss or kidney problems) to tobramycin or any other aminoglycosides, such as amikacin, streptomycin, gentamicin, or neomycin, 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, sulfites, foods, preservatives or dyes.

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 into 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.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney disease or kidney problems
- muscular disorders (e.g. myasthenia gravis, Parkinson's disease)
- cystic fibrosis
- hearing problems.

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

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 VIATRIS may interfere with each other. These include:

- fluid tablets (diuretics) e.g. furosemide (frusemide), etacrynic acid, bumetanide or other potent diuretics.
- neurotoxic or nephrotoxic antibiotics such as aminoglycosides, cephaloridine, polymixin B, colistin, cisplatin and vancomycin.
- other antibiotics to treat infections, including ciclosporins and cephalosporins, particularly cefalotin
- amphotericin B (amphotericin), a medicine used to treat fungal infections.
- opioid analgesics (e.g. codeine, morphine, pethidine, fentanyl)
- some general anaesthetic agents
- muscle relaxants (e.g. succinylcholine)
- some medicines used to prevent blood clots, e.g. warfarin, phenindione
- any drug that may cause kidney or hearing problems
- neostigmine and pyridostigmine, medicines used to treat myasthenia gravis.

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 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 VIATRIS 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 VIATRIS 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 experience side effects tell your doctor or nurse immediately, or if you are not already in hospital, go to the Accident & Emergency Department at your nearest hospital.

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 contact the Poisons Information Centre for advice (telephone 13 11 26).

You may need urgent medical attention.

While you are being given TOBRAMYCIN VIATRIS

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

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

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.

Things to be careful of

Be careful driving or operating machinery until you know how TOBRAMYCIN VIATRIS 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. Children should be careful performing activities requiring attention such as riding bicycles or climbing.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

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 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

If you are dehydrated you may have an increased chance of getting 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
- dizziness or headache
- fever
- nausea or vomiting
- sore mouth and gums
- pain at the injection site.

- rash or itchiness
- signs of anaemia, such as tiredness, being short of breath and looking pale
- confusion or disorientation.

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
- vertigo
- muscle weakness
- increased or 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 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.

After using TOBRAMYCIN VIATRIS

Storage

TOBRAMYCIN VIATRIS 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 VIATRIS is a clear, colourless liquid filled in a glass vial.

Ingredients

TOBRAMYCIN VIATRIS contains tobramycin as the active ingredient.

It also contains the following inactive ingredients:

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

This medicine contains sulfites and residual apramycin and kanamycin B.

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

Supplier

TOBRAMYCIN VIATRIS is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Australian registration numbers:

TOBRAMYCIN VIATRIS 80 mg/2 mL: AUST R 234429

This leaflet was prepared in June 2022.

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