

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 being given TOBRAMYCIN VIATRIS against the benefits expected for you.

If you have any concerns about being given 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, streptomycin, gentamicin or 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 or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- sulfites
- foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend 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 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 the possible risks and benefits of being given it during breastfeeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

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

- cystic fibrosis
- hearing problems, or if you or your family have a mitochondrial mutation disease, or loss of hearing due to antibiotic medicines; certain mitochondrial mutations may increase your risk of hearing loss with this product.

If you have not told your doctor or pharmacist about any of the above, tell them 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 buy 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, etacrynic acid, bumetanide.
- other antibiotics to treat infections, including ciclosporins and cephalosporins, particularly cefalotin
- cisplatin, a medicine used to treat cancer
- amphotericin B, an antifungal medicine
- opioid analgesics (e.g. codeine, morphine, pethidine, fentanyl)
- some general anaesthetic agents
- muscle relaxants such as suxamethonium
- 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

medicine, or you may need to be given different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while receiving tobramycin.

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 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.

However, if you experience severe side effects tell your doctor or nurse immediately, or if you are not already in hospital, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at the nearest hospital.

You may need urgent medical attention.

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.

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

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are being given TOBRAMYCIN VIATRIS.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given this medicine.

It may affect other medicines used during surgery.

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

If you develop a serious rash (peeling, blistering and shedding of the skin, often with fever) during treatment with this medicine, tell your doctor or nurse immediately.

Things to be careful of

Be careful driving or operating machinery until you know how TOBRAMYCIN VIATRIS affects you.

This medicine may cause tiredness, dizziness or drowsiness 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 nurse as soon as possible if you do not feel well while you are being treated with 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 treatment 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 nurse 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
- dizziness or headache
- fever
- nausea or vomiting
- sore mouth and gums
- oral thrush

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

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 (tinnitus)
- 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.

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
- water for injections.

This medicine contains sulfites and residual apramycin and kanamycin B.

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

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