

TOBRAMYCIN VIATRIS

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about receiving TOBRAMYCIN VIATRIS, speak to your doctor or pharmacist.

1. Why am I being given TOBRAMYCIN VIATRIS?

TOBRAMYCIN VIATRIS contains the active ingredient tobramycin. TOBRAMYCIN VIATRIS is used for the treatment of serious infections caused by bacteria.

For more information, see Section [1. Why am I being given TOBRAMYCIN VIATRIS?](#) in the full CMI.

2. What should I know before I am given TOBRAMYCIN VIATRIS?

Do not receive TOBRAMYCIN VIATRIS if you have ever had an allergic reaction to tobramycin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions including kidney problems, muscular disorders, cystic fibrosis, hearing problems or mitochondrial disorders; take any other medicines,

or are pregnant or breastfeeding or plan to become pregnant or breastfeed.

For more information, see Section [2. What should I know before I am given TOBRAMYCIN VIATRIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TOBRAMYCIN VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given TOBRAMYCIN VIATRIS?

- Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and kidney function.
- Tobramycin is given as an injection into a muscle, or as a slow injection (drip) into a vein (intravenously) and should only be given by a doctor or nurse.

More instructions can be found in Section [4. How am I given TOBRAMYCIN VIATRIS?](#) in the full CMI.

5. What should I know while being given TOBRAMYCIN VIATRIS?

Things you should do	<ul style="list-style-type: none">• Tell your doctor, dentist or pharmacist you visit that you are being given TOBRAMYCIN VIATRIS.• 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 TOBRAMYCIN VIATRIS, tell your doctor or nurse immediately.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how TOBRAMYCIN VIATRIS affects you.

For more information, see Section [5. What should I know while being given TOBRAMYCIN VIATRIS?](#) in the full CMI.

6. Are there any side effects?

Tiredness, weakness; tingling, numbness, pins and needles or pain in the hands or feet; dizziness; headache; fever; nausea, vomiting; sore mouth and gums; pain at the injection site; rash or itching; signs of anaemia (tiredness, being short of breath, looking pale); mental confusion, disorientation. Serious side effects may include signs of an allergic reaction (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 or swallowing); severe flaking or peeling of the skin; severe skin reaction with painful red areas, large blisters and peeling of layers of skin accompanied by fever and chills, aching muscles and generally feeling unwell; severe blisters and bleeding in the lips, eyes, mouth, nose and genitals; hearing problems such as hearing loss, ringing or unusual sounds in the ears; vertigo; roaring in the ears even after stopping treatment for several weeks; double vision; drooping eyelids, difficulty in speaking and swallowing, muscle weakness in the arms or legs; muscle cramps; increased or decreased urination; diarrhoea even several weeks after stopping treatment; bleeding or bruising more easily than normal. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

TOBRAMYCIN VIATRIS

Active ingredient(s): *tobramycin*

Consumer Medicine Information (CMI)

This leaflet provides important information about how TOBRAMYCIN VIATRIS is given. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about receiving TOBRAMYCIN VIATRIS.**

Where to find information in this leaflet:

- [1. Why am I being given TOBRAMYCIN VIATRIS?](#)
- [2. What should I know before I am given TOBRAMYCIN VIATRIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I being given TOBRAMYCIN VIATRIS?](#)
- [5. What should I know while being given TOBRAMYCIN VIATRIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given TOBRAMYCIN VIATRIS?

TOBRAMYCIN VIATRIS contains the active ingredient tobramycin. TOBRAMYCIN VIATRIS 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 VIATRIS is used to treat serious bacterial infections, including:

- meningitis (infection of the brain)
- septicaemia (infection of the blood)
- neonatal sepsis (infection in infants)
- lower respiratory tract infections
- gastrointestinal tract infections
- bone, skin and skin structure infections, including infected burns
- urinary tract infections.

Ask your doctor if you have any questions about why TOBRAMYCIN VIATRIS has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I am being given TOBRAMYCIN VIATRIS?

Warnings

Do not receive TOBRAMYCIN VIATRIS if:

- you are allergic 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, vancomycin, colistin, cisplatin 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.

Always check the ingredients to make sure you can receive TOBRAMYCIN VIATRIS.

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.

Check with your doctor if you:

- have allergies to:
 - any other medicines
 - sulfites
 - foods, preservatives or dyes.
- have or have had any other medical conditions, especially the following:
 - kidney disease or kidney problems

- muscular disorders, like
 - myasthenia gravis (a condition in which the muscles become weak and tire easily)
 - Parkinson's disease (a brain condition affecting movement)
- cystic fibrosis (a conditions that causes breathing and digestion problems)
- 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.
- take any medicines for any other condition

If you have not told your doctor or pharmacist about any of the above, tell them before you are given TOBRAMYCIN VIATRIS.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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

Like most aminoglycoside antibiotics, tobramycin is not recommended for use during pregnancy. TOBRAMYCIN VIATRIS is potentially harmful to the fetus. 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.

3. What if I am taking other medicines?

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

Some medicines may interfere with TOBRAMYCIN VIATRIS and affect how it works. These include:

- fluid tablets (diuretics) e.g. furosemide, etacrynic acid, bumetanide.
- other antibiotics to treat infections, including penicillins, cephalosporins, particularly cefalotin, and aminoglycosides vancomycin, amikacin, gentamicin, as well as colistin and neomycin
- ciclosporins, a medicine used to stop organ rejection in transplant patients
- cisplatin, a medicine used to treat cancer
- amphotericin B, an antifungal medicine

- opioid pain medicine (e.g. codeine, morphine, pethidine, fentanyl)
- methoxyflurane an inhaled medicine for strong pain relief
- muscle relaxants such as suxamethonium
- medicines used to prevent blood clots, e.g. warfarin, phenindione
- 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 TOBRAMYCIN VIATRIS, or you may need to be given different medicines. Your doctor or pharmacist will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TOBRAMYCIN VIATRIS.

4. How am I being given TOBRAMYCIN VIATRIS?

How much TOBRAMYCIN VIATRIS 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 TOBRAMYCIN VIATRIS is given

- Tobramycin is given as an injection into a muscle or as a slow injection (drip) into a vein (intravenously).

Tobramycin should only be given by a doctor or nurse.

If you are given too much TOBRAMYCIN VIATRIS

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 any dizziness, ringing or unusual sounds in the ears, vertigo or change in hearing, or 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.

Do this even if there are no signs of discomfort or poisoning.

Symptoms of a tobramycin overdose may include the side effects listed below in the [6. Are there any side effects?](#) section, but are usually of a more severe nature.

5. What should I know while using TOBRAMYCIN VIATRIS?

Things your doctor should do

Your doctor or nurse should take regular blood and urine samples while you are receiving TOBRAMYCIN VIATRIS 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 received TOBRAMYCIN VIATRIS.
- Tell any other doctors, dentists, and pharmacists who are treating you that you received TOBRAMYCIN VIATRIS.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are being given TOBRAMYCIN VIATRIS.

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

- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how TOBRAMYCIN VIATRIS affects you.

TOBRAMYCIN VIATRIS 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.

Drinking alcohol

No information available.

Looking after your medicine

TOBRAMYCIN VIATRIS will be stored in the hospital ward or pharmacy protected from light, in a cool dry place where the temperature stays below 25°C.

Getting rid of any unwanted medicine

Any unwanted medicine will be disposed of in safe manner by doctor, nurse or pharmacist.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

If you have myasthenia gravis, are dehydrated, are over 65 years of age 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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• tiredness or weakness• tingling, numbness or pain of the hand or feet, or pins and needles• dizziness or headache• fever	Speak to your doctor if you have any of these less serious side effects.

Less serious side effects	What to do
<ul style="list-style-type: none"> • nausea or vomiting • 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 or disorientation. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 • severe flaking or peeling of the skin • severe skin reaction which starts with painful red areas, then large 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>blisters and ends with peeling of layers of skin which is accompanied by fever and chills, aching muscles and generally feeling unwell</p> <ul style="list-style-type: none"> ● rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals ● hearing problems such as hearing loss, ringing or unusual sounds in the ears (tinnitus), vertigo, roaring in the ears even after stopping treatment for several weeks ● double vision ● drooping eyelids ● difficulty in speaking and swallowing, muscle weakness in the arms or legs, muscle cramps ● vertigo ● difficulty breathing ● increased or decreased urination 	

Serious side effects	What to do
<ul style="list-style-type: none"> • diarrhoea, even after stopping antibiotics for several weeks • bleeding or bruising more easily than normal. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What TOBRAMYCIN VIATRIS contains

Active ingredient (main ingredient)	Tobramycin 80 mg/2 mL
Other ingredients (inactive ingredients)	disodium edetate sodium bisulfite sulfuric acid sodium hydroxide water for injections.
Potential allergens	sulfites residual apramycin and kanamycin B

Do not take TOBRAMYCIN VIATRIS if you are allergic to any of these ingredients.

What TOBRAMYCIN VIATRIS looks like

TOBRAMYCIN VIATRIS is a clear, colourless liquid filled in a glass vial (AUST R 234429).

TOBRAMYCIN VIATRIS is available in a pack containing 5 vials.

Who distributes TOBRAMYCIN VIATRIS

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

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