

TOBRAMYCIN WKT

Consumer Medicine Information (CMI) Summary

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

1. Why am I using TOBRAMYCIN WKT?

TOBRAMYCIN WKT contains the active ingredient tobramycin. Tobramycin is antibacterial agent, which is active against a common lung infection that occurs in patients with cystic fibrosis (CF).

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

2. What should I know before I use TOBRAMYCIN WKT?

Do not use 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, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with TOBRAMYCIN WKT 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 do I use TOBRAMYCIN WKT?

- Inhale TOBRAMYCIN WKT as prescribed by your doctor. Breathe normally through the mouthpiece of the nebuliser until all of the solution is gone and there is no mist being produced.
- The recommended dose of TOBRAMYCIN WKT is one ampoule twice daily for 28 days, followed by 28 days of not taking TOBRAMYCIN WKT. Repeat the 28 day on drug/28 day off drug cycle.

More instructions can be found in Section [4. How do I use TOBRAMYCIN WKT?](#) in the full CMI.

5. What should I know while using TOBRAMYCIN WKT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using TOBRAMYCIN WKT inhaler.• Tell your doctor if you are pregnant, intend to become pregnant, are breast feeding or plan to breast-feed.• Tell your doctor if you have any other medical conditions.• If you plan to have surgery with a general anaesthetic, tell your doctor /dentist that you are using TOBRAMYCIN WKT
Things you should not do	<ul style="list-style-type: none">• Do not use this medicine if the solution is cloudy or if there are particles in the solution.• Do not use any TOBRAMYCIN WKT which has been stored at room temperature for more than 28 days.• Do not dilute or mix other medications with TOBRAMYCIN WKT in the nebuliser.• Never use a dirty or clogged nebulizer and do not share your nebuliser with other people.• Do not give TOBRAMYCIN WKT to anyone else, or use it to treat any other complaints.• Do not stop using TOBRAMYCIN WKT or lower the dosage, without checking with your doctor or pharmacist.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how TOBRAMYCIN WKT affects you.• TOBRAMYCIN WKT may cause dizziness, ringing in the ears, or light-headedness in some people.
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol, you may experience dizziness or light-headedness.
Looking after your medicine	<ul style="list-style-type: none">• Store TOBRAMYCIN WKT between 2-8°C in the refrigerator. Opened ampoules must be used immediately.• You can store the foil pouches (opened or unopened) at room temperature (up to 25°C) for up to 28 days.

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

6. Are there any side effects?

Common side effects include: runny or stuffy nose, sneezing, voice alteration, loss of voice, difficulty swallowing (laryngitis), discoloured substance you cough up (sputum), decreased lung function test results, muscle pain, generally feeling unwell, itching or itchy rash, sore throat, disturbed sense of taste, anorexia, vomiting, nausea, diarrhoea, digestive changes, yeast mouth infection, sweating.

Serious side effects include: ringing, noises (such as hissing) or pain in the ears, hearing loss, dizziness, light-headedness, clumsiness, lack of coordination, chest pain or tightness, increased coughing, wheezing or difficulty in breathing, generally feeling unwell, discolored sputum, diarrhoea or abdominal pain, even several weeks after use, worsening of your lung disease. Signs of an allergic reaction include: swelling of the face, lips, mouth, throat or tongue, difficulty in swallowing or breathing, shortness of breath, skin rash, wheezing or coughing or chest tightness.

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 WKT

Active ingredient: tobramycin

Consumer Medicine Information (CMI)

This leaflet provides important information about using TOBRAMYCIN WKT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TOBRAMYCIN WKT.**

Where to find information in this leaflet:

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

1. Why am I using TOBRAMYCIN WKT?

TOBRAMYCIN WKT contains the active ingredient tobramycin. Tobramycin belongs to a class of antibiotics called aminoglycosides. It works by killing or stopping the growth of the bacteria that cause infection. The bacterium that commonly infects the lung of most cystic fibrosis patients at some stage of their lives is *Pseudomonas aeruginosa*. It is one of the most damaging bacteria for people with CF.

TOBRAMYCIN WKT contains an antibacterial agent which is active against a common lung infection that occurs in patients with cystic fibrosis (CF).

If the infection is not properly fought, it will continue to damage your lungs, causing further problems with your breathing.

TOBRAMYCIN WKT solution has been specially formulated for administration by inhalation via a nebuliser and compressor. When you inhale TOBRAMYCIN WKT the antibiotic can get straight into your lungs to fight against the infection and to improve your breathing.

Although TOBRAMYCIN WKT does not cure your condition, it does help control it. TOBRAMYCIN WKT is not recommended for use in children younger than 6 years of age.

2. What should I know before I use TOBRAMYCIN WKT?

Warnings

Do not use TOBRAMYCIN WKT if:

- you are allergic to tobramycin, or any antibiotics that belong to the aminoglycoside group (e.g. amikacin, gentamicin, neomycin, or streptomycin), or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

The symptoms of an allergic reaction may include: skin rash, itchiness, shortness of breath, wheezing or difficulty breathing, swelling of the lips, tongue, face or other parts of the body.

Do not give TOBRAMYCIN WKT to a child below the age of 6, unless directed to by the child's doctor or pharmacist.

TOBRAMYCIN WKT is not recommended for use in children under 6 years.

Check with your doctor if you:

- have kidney problems
- have hearing problems, including noises in the ears and dizziness
- have unusual difficulty in breathing with wheezing or coughing, chest tightness
- have trouble with your balance or dizzy spells
- have problems with nerve or muscle function
- have muscle weakness that lasts, or becomes worse in time, a symptom mostly related to conditions such as Parkinson's disease (a brain condition affecting movement)
- have myasthenia (a condition in which the muscles become weak and tire easily).
- have any other medical conditions
- take any medicines for any other condition
- have allergies to any other medicines, substance or foods
- are aged 65 years or older, as your doctor may perform additional tests to decide if TOBRAMYCIN WKT is right for you.

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

Check with your doctor if you are pregnant or intend to become pregnant.

TOBRAMYCIN WKT may affect your developing baby if you use it during pregnancy. Your doctor or pharmacist will discuss the possible risks and benefits of using TOBRAMYCIN WKT during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby. Your doctor or pharmacist will discuss the risks and benefits of using TOBRAMYCIN WKT during breast-feeding.

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 and TOBRAMYCIN WKT may interfere with each other. These include:

- diuretics (fluid tablets), especially those that contain frusemide, or ethacrynic acid
- urea
- intravenous mannitol
- tobramycin or another aminoglycoside antibiotic by injection (e.g. amikacin, gentamicin, neomycin, streptomycin)

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 WKT.

4. How do I use TOBRAMYCIN WKT?

How much to use

- Inhale TOBRAMYCIN WKT only when prescribed by your doctor.
- Do not exceed the recommended dose. The recommended dose of TOBRAMYCIN WKT is one 300 mg/5 mL ampoule twice daily (every 12 hours) for 28 days.
- This is followed by 28 days of not taking TOBRAMYCIN WKT.
- Repeat the 28 day on drug/28 day off drug cycle.
- Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.
- If you do not understand the instructions on the carton or leaflet, ask your doctor or pharmacist for help.
- TOBRAMYCIN WKT solution is contained in a ready-to-use ampoule and is specifically formulated for inhalation therapy using a PARI LC PLUS reusable nebuliser and a compressor. It is important that your nebuliser and compressor function properly before you start your TOBRAMYCIN WKT therapy.
- Breathe normally through the mouthpiece of the nebuliser until all of the TOBRAMYCIN WKT solution is gone and there is no longer any mist being produced. This is usually for a period of approximately 15 minutes. You may sit or stand upright while inhaling your dose.
- If you are not sure how to use a nebuliser, ask your doctor or pharmacist. Children should only use a nebuliser on medical advice and with the help of an adult.

When to use TOBRAMYCIN WKT

- If you are taking several different inhaled treatments and performing therapies for cystic fibrosis, you should use TOBRAMYCIN WKT last.
- Use TOBRAMYCIN WKT at about the same time every day. Using your medicine at the same time each day will help you remember when to take it.
- Inhale TOBRAMYCIN WKT twice daily.
- Doses should be administered as close to 12 hours apart as possible and not less than 6 hours apart.

How to inhale TOBRAMYCIN WKT

1. Wash your hands thoroughly with soap and water and fully dry hands.
2. Just before use, cut or tear open the foil pouch and remove one TOBRAMYCIN WKT ampoule by gently pulling apart one of the attached ampoules at the bottom tabs.
3. Put the other ampoule(s) back in the foil pouch and keep it in the refrigerator.
4. Layout all the pieces of your nebuliser on a clean, dry paper or cloth towel:
 - a. nebuliser top
 - b. nebuliser cup
 - c. inspiratory valve cap
 - d. mouthpiece with valve tubing
5. Check that you have the suitable compressor, and tubing to connect the nebuliser and compressor.
6. Follow the appropriate instructions for use for your type of nebuliser. You must read the leaflet provided with the nebuliser by the manufacturer.
7. Check that your nebuliser and compressor are working properly according to the manufacturer's instructions before you start to take your medicine.
8. Remove the nebuliser top from the nebuliser cup by twisting the top anticlockwise and then lifting it.
9. Place the nebuliser top on the towel and stand the nebuliser cup upright on the towel.
10. Connect one end of the tubing to the compressor air outlet. Make sure that the tubing fits snugly. Plug the compressor into the electrical outlet.
11. Open the TOBRAMYCIN WKT ampoule by holding the bottom tab with one hand and twisting off the top with your other hand.
12. Squeeze all the contents of the ampoule into the nebuliser cup.
13. Replace the nebuliser top (a), put the mouthpiece (d) and the inspiratory valve cap (c) in place on the nebuliser, and then connect the compressor as indicated in your nebuliser leaflet.
14. Turn on the compressor. Check that there is a steady mist coming from the mouthpiece. If there is no mist, check all tubing connections and that the compressor is working properly.
15. Sit or stand in an upright position so that you can breathe normally.
16. Place the mouthpiece between your teeth and on top of your tongue. Breathe normally, but only through your mouth (you may use a nose clip if your doctor agrees). Try not to block the air flow with your tongue.
17. Continue until all of the TOBRAMYCIN WKT solution is gone and there is no longer any mist being produced. It should take about 10-15 minutes to inhale all of the treatment. You may hear a spluttering sound when the nebuliser cup is empty.
18. Clean, disinfect, and dry your nebuliser after each use, according to the manufacturer's instructions. It may not work as well if it gets dirty.

If you forget to use TOBRAMYCIN WKT

If there are at least 6 hours to your next dose, use TOBRAMYCIN WKT and then go back to using your medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting any unwanted side effects.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

If you use too much TOBRAMYCIN WKT

If you think that you have used too much TOBRAMYCIN WKT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**); or
- contact your doctor; or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Signs of an overdose may include:

- loss of balance
- hearing problems
- breathing problems
- kidney problems
- difficulty with nerve and muscle function
- dizziness
- ringing in the ears

5. What should I know while using TOBRAMYCIN WKT?

Things you should do

Keep TOBRAMYCIN WKT in the foil pouch (opened or unopened) in the pack until it is time for your dose. If you take the medication out of the pouch it will not keep well. TOBRAMYCIN WKT is sensitive to very strong light.

Consult the package insert supplied with TOBRAMYCIN WKT for detailed information and diagrams describing the correct use and care of your inhalation equipment and instructions on how to use TOBRAMYCIN WKT.

If you are interrupted, or need to cough or rest during your TOBRAMYCIN WKT treatment, turn off the compressor to save your medicine. Turn the compressor on again when you are ready to restart your treatment.

If you become pregnant while using TOBRAMYCIN WKT tell your doctor immediately.

Tell any other doctors, dentists, and pharmacists who are treating you that you are using TOBRAMYCIN WKT.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using TOBRAMYCIN WKT.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are using TOBRAMYCIN WKT.

Things you should not do

- Do not use this medicine if the solution is cloudy or if there are particles in the solution.
- Do not use any TOBRAMYCIN WKT which you have stored at room temperature for more than 28 days.
- Do not dilute or mix other medications, with TOBRAMYCIN WKT in the nebuliser.
- Never use a dirty or clogged nebuliser.
- Do not share your nebuliser with other people.
- Do not give TOBRAMYCIN WKT to anyone else, even if they have the same condition as you.
- Do not use TOBRAMYCIN WKT to treat any other complaints unless your doctor tells you to.
- Do not stop using TOBRAMYCIN WKT or lower the dosage, without checking with your doctor or pharmacist.

Things to be careful of

- Inhaling medicines can cause chest tightness and wheezing. This may happen immediately after inhaling this medicine.
- If you have swallowed TOBRAMYCIN WKT in error, tell your doctor as soon as possible. When swallowed, this medicine will not harm you, but this medicine will not work as it is meant to.

Driving or using machines

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

TOBRAMYCIN WKT may cause dizziness, ringing in the ears, or light-headedness in some people.

If you feel dizzy or light-headed after using TOBRAMYCIN WKT do not drive, operate machinery, use tools, or do anything else that could be dangerous if you are dizzy or lightheaded.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, you may experience dizziness or light-headedness.

Looking after your medicine

Store TOBRAMYCIN WKT between 2-8°C in the refrigerator.

If you do not have a refrigerator available (e.g. when transporting TOBRAMYCIN WKT), you can store the foil pouches (opened or unopened) at room temperature (up to 25°C) for up to 28 days.

Do not store any opened ampoules of TOBRAMYCIN WKT **Once opened, the solution should be used immediately.**

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink; or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Runny or stuffy nose, sneezing• voice alteration, loss of voice• sore throat• difficulty swallowing (laryngitis)• discolouration of the substance you cough up (sputum)• decreased lung functions test results• muscle pain• generally feeling unwell• itching or itchy rash• disturbed sense of taste• anorexia, vomiting, nausea, diarrhoea, digestive changes, yeast mouth infection• sweating	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• ringing in the ears or hearing loss• noises in the ears (such as hissing) or pain• dizziness• light-headedness• clumsiness or lack of coordination• chest pain or chest tightness• increased coughing, wheezing or difficulty in breathing• generally feeling unwell• discoloration of the substance you cough up (sputum)• diarrhoea or abdominal pain, even several weeks after use <p>Signs of an allergic reaction, including:</p> <ul style="list-style-type: none">• swelling of the face, lips, mouth, throat or tongue, difficulty in swallowing or breathing• shortness of breath• skin rash• unusual difficulty in breathing, with wheezing, coughing or chest tightness• worsening of your underlying lung disease.	<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>

If you are taking tobramycin or another aminoglycoside antibiotic by injection, it may sometimes cause hearing loss, dizziness, and kidney damage, and may harm an unborn child.

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. It is not addictive.

Each 5 mL single dose ampoule contains tobramycin 300 mg.

What TOBRAMYCIN WKT contains

Active ingredient (main ingredient)	tobramycin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">•sodium chloride•water for injections•nitrogen•sulfuric acid[#]•sodium hydroxide[#]

[#]These ingredients may have been added to adjust the pH of the final solution.

Do not take this medicine if you are allergic to any of these ingredients.

TOBRAMYCIN WKT does not contain preservatives, lactose, sucrose, gluten, tartrazine or any other azo dyes.

What TOBRAMYCIN WKT looks like

Each carton of TOBRAMYCIN WKT contains 56 single- dose ampoules (a 28-day supply). The ampoules are in 8 pouches with 7 ampoules in each pouch.

TOBRAMYCIN WKT is supplied in clear, single-use low density polyethylene ampoules that are packaged in foil pouches. The solution is clear and particle free. (AUST R 279353).

Who distributes TOBRAMYCIN WKT

Luminarie Pty Ltd
Level 5, 4 Columbia Ct,
BAULKHAM HILLS NSW 2153

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