

# TOBRAMYCIN WOCKHARDT

## Solution for inhalation

*Tobramycin*

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### Consumer Medicine Information

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#### What is in this leaflet

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This leaflet answers some common questions about TOBRAMYCIN WOCKHARDT

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

**You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.**

All medicines have benefits and risks. Your doctor has weighed the risks of using TOBRAMYCIN WOCKHARDT against the benefits it is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

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#### What TOBRAMYCIN WOCKHARDT is used for

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

Tobramycin belongs to a class of antibiotics called aminoglycosides.

It works by killing or stopping the growth of the bacteria that cause the 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.

Some people do not get this infection until later on in their lives, while others get very young. If the infection is not properly fought, it will continue to damage your lungs, causing further problems with your breathing. TOBRAMYCIN WOCKHARDT solution has been specially formulated for administration by inhalation via a nebuliser and compressor. When you inhale TOBRAMYCIN WOCKHARDT the antibiotic can get straight into your lungs to fight against the infection and to improve your breathing.

**For best results, please use TOBRAMYCIN WOCKHARDT as this leaflet instructs you.**

Although TOBRAMYCIN WOCKHARDT does not cure your condition, it does help control it. TOBRAMYCIN WOCKHARDT is not recommended for use in children younger than 6 years of age, as there have been no studies of its effects in this age group.

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

Your doctor may have prescribed TOBRAMYCIN WOCKHARDT for another reason.

This medicine is available only with a doctor's prescription. It is not addictive.

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#### Before you use TOBRAMYCIN WOCKHARDT

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*When you must not use it*

**Do not use TOBRAMYCIN WOCKHARDT if you have an allergy to:**

- TOBRAMYCIN WOCKHARDT or any other tobramycin medicine, e.g. Nebcin®
- any antibiotics that belong to the aminoglycoside group (e.g. amikacin, gentamicin, neomycin, or streptomycin)
- any of the other ingredients listed at the end of this leaflet.

**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.

**If you think that you may be allergic, ask your doctor for advice.**

**Do not use TOBRAMYCIN WOCKHARDT**

- after the expiry date printed on the pack has passed
- if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist. If you use this medicine

after the expiry date has passed, it may not work as well.

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

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

If you are not sure whether you or your child should start using TOBRAMYCIN WOCKHARDT talk to your doctor or pharmacist. If you are not sure whether you should use this medicine, talk to your doctor.

*Before you start to use it*

**Tell your doctor if you are pregnant or intend to become pregnant.**

TOBRAMYCIN WOCKHARDT 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 WOCKHARDT during pregnancy.

**Tell your doctor if you are breast feeding or plan to breast-feed.**

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 WOCKHARDT during breast-feeding.

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

- kidney problems
- hearing problems, including noises in the ears and dizziness
- unusual difficulty in breathing with wheezing or coughing, chest tightness
- trouble with your balance
- dizzy spells
- problems with nerve or muscle function
- muscle weakness that lasts, or becomes worse in time, a

symptom mostly related to conditions such as Parkinson's disease (a condition of the brain affecting movement) or myasthenia (a condition in which the muscles become weak and tire easily).

**Tell your doctor if you have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

Your doctor will want to know if you are prone to allergies.

If you are aged 65 years or older, your doctor may perform additional tests to decide if TOBRAMYCIN WOCKHARDT is right for you.

If you have not told your doctor about any of the above, tell them before you start using TOBRAMYCIN WOCKHARDT.

*Taking other medicines*

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

Some medicines and TOBRAMYCIN WOCKHARDT 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).

These medicines may be affected by TOBRAMYCIN WOCKHARDT or may affect how well it works. You may need different amounts of your medicine, or you may need to take 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 using TOBRAMYCIN WOCKHARDT.

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## How to use TOBRAMYCIN WOCKHARDT

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*How much to use*

**Inhale TOBRAMYCIN WOCKHARDT only when prescribed by your doctor.**

Do not exceed the recommended dose. The recommended dose of TOBRAMYCIN WOCKHARDT 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 WOCKHARDT.

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.**

*How to use it*

TOBRAMYCIN WOCKHARDT 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 WOCKHARDT therapy.

**Breathe normally through the mouthpiece of the nebuliser until all of the TOBRAMYCIN WOCKHARDT 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 it*

**Please check the order of medications with your doctor.**

If you are taking several different inhaled treatments and performing therapies for cystic fibrosis, you should use TOBRAMYCIN WOCKHARDT LAST.

Use TOBRAMYCIN WOCKHARDT 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 WOCKHARDT 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 WOCKHARDT*

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 WOCKHARDT 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. Lay out 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 WOCKHARDT 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 airflow with your tongue.

17. Continue until all of the TOBRAMYCIN WOCKHARDT 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.

### *How long to use it*

**Use TOBRAMYCIN WOCKHARDT twice daily every day for 28 days, followed by a 28 day period off TOBRAMYCIN WOCKHARDT.**

**Continue using TOBRAMYCIN WOCKHARDT in these 28 day on/28 day off cycles for as long as your doctor or pharmacist tells you.**

**If you have any questions about how long to use TOBRAMYCIN WOCKHARDT ask your doctor or pharmacist.**

### *If you forget to use it*

**If there are at least 6 hours to your next dose, use TOBRAMYCIN WOCKHARDT 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 have your next TOBRAMYCIN WOCKHARDT dose when you are meant to.**

**Do not have a double dose to make up for the dose that you missed.**

This may increase the chance of you getting an unwanted side effect.

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

**If you have trouble remembering to use your medicine, ask your pharmacist for some hints.**

### *If you use too much (overdose)*

**Immediately telephone your doctor, or Poisons Information Centre (telephone Australia 131126 or New Zealand 0800 POISON or 0800 764 766) for**

advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Tobramycin Wockhardt.

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

Signs of an overdose may include:

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

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## While you are using TOBRAMYCIN WOCKHARDT

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### *Things you must do*

Keep TOBRAMYCIN WOCKHARDT 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 Wockhardt is sensitive to very strong light.

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

If you are interrupted, or need to cough or rest during your TOBRAMYCIN WOCKHARDT 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 WOCKHARDT tell your doctor immediately.

Tell any other doctors, dentists, and pharmacists who are treating

you that you are using TOBRAMYCIN WOCKHARDT.

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

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

### *Things you must 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 WOCKHARDT which you have stored at room temperature for more than 28 days. Do not dilute or mix other medications, with TOBRAMYCIN WOCKHARDT in the nebuliser.

Never use a dirty or clogged nebuliser.

Do not share your nebuliser with other people.

Do not give TOBRAMYCIN WOCKHARDT to anyone else, even if they have the same condition as you.

Do not use TOBRAMYCIN WOCKHARDT to treat any other complaints unless your doctor tells you to.

Do not stop using TOBRAMYCIN WOCKHARDT 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 WOCKHARDT 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.

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

TOBRAMYCIN WOCKHARDT may cause dizziness, ringing in the ears, or light-headedness in some people. If you drink alcohol, dizziness or light-headedness may be worse.

**If you feel dizzy or light-headed after using TOBRAMYCIN WOCKHARDT do not drive.**

Make sure you know how you react to TOBRAMYCIN WOCKHARDT before you drive a car, operate machinery, use tools, or do anything else that could be dangerous if you are dizzy or light-headed.

**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.**

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## SIDE EFFECTS

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TOBRAMYCIN WOCKHARDT helps most people with cystic fibrosis, but can cause side effects in a few people.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using TOBRAMYCIN WOCKHARDT.

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.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor if you notice any of the following and that worry you:**

- runny or stuffy nose
- sneezing

- voice alteration with or without a sore throat
- difficulty swallowing (laryngitis)
- discolouration of the substance you cough up (sputum)
- decreased results for the tests of lung function
- muscle pain
- generally feeling unwell
- itching or itchy rash
- loss of your voice
- sore throat
- disturbed sense of taste.

**Tell your doctor immediately if you notice any of the following:**

- ringing in the ears
- hearing loss
- noises in the ears (such as hissing)
- dizziness
- light-headedness
- clumsiness and 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).

These may be serious side effects of TOBRAMYCIN WOCKHARDT. You may need urgent medical attention. Serious side effects are rare.

**Tell your doctor immediately or go to accident and emergency at your nearest hospital if you notice any of the following:**

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- shortness of breath
- skin rash
- unusual difficulty in breathing, with wheezing or coughing or chest tightness
- worsening of your underlying lung Disease.

These are serious side effects. If you have them, you may have had a serious allergic reaction to TOBRAMYCIN WOCKHARDT.

You may need urgent medical attention or hospitalisation.

**Tell your doctor if you notice anything that is making you feel unwell.**

Other side effects not listed may occur in some patients.

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## After using TOBRAMYCIN WOCKHARDT

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### *Cleaning*

**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.

### *Storage*

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

If you do not have a refrigerator available (for example, when you are transporting TOBRAMYCIN WOCKHARDT), 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 WOCKHARDT**

Once opened, the solution should be used immediately.

**Do not leave this medicine in the car on hot days or on window sills.**

Heat and intense light can destroy some medicines.

**Keep TOBRAMYCIN WOCKHARDT where children cannot reach it.**

A locked cupboard at least one and a half meters above the ground is a good place to store medicines.

## *Disposal*

**If your doctor tells you to stop using TOBRAMYCIN WOCKHARDT or the solution has passed its expiry date, ask your pharmacist what to do with any that is leftover.**

Medicines should not be disposed of in household waste. These measures will help to protect the environment.

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## Product description

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### *What it looks like*

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

TOBRAMYCIN WOCKHARDT is supplied in clear, single-use low density polyethylene ampoule that is packaged in foil pouches.

### *Ingredients*

#### **Active ingredient:**

Each 5 mL single dose ampoule contains tobramycin 300 mg.

#### **Inactive ingredients:**

- sodium chloride
- water for injections
- nitrogen
- sulfuric acid#
- sodium hydroxide#

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

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

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## Sponsor

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Numbers*

279354

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