

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 TOBI?

TOBI contains the active ingredient tobramycin. TOBI is used for common lung infection that occurs in patients with cystic fibrosis (CF). For more information, see Section [1. Why am I using TOBI?](#) in the full CMI.

2. What should I know before I use TOBI?

Do not use if you have ever had an allergic reaction to TOBI 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 TOBI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with TOBI 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 TOBI?

- The recommended dose of TOBI is one 300 mg/5 mL ampoule twice daily (every 12 hours) for 28 days.
- To use TOBI, breathe normally through the mouthpiece of the nebuliser until all of the TOBI solution is gone and there is no longer any mist being produced.

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

5. What should I know while using TOBI?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using TOBI. • Keep TOBI in the foil pouch (opened or unopened) in the pack until it is time for your dose.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not use this medicine if the solution is cloudy or if there are particles in the solution.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or operating machinery until you know how TOBI affects you. • If you feel dizzy or light-headed after using TOBI, do not drive.
Drinking alcohol	<ul style="list-style-type: none"> • TOBI may cause dizziness, ringing in the ears, or light-headedness in some people. If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	<ul style="list-style-type: none"> • Store TOBI between 2-8°C in the refrigerator.

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

6. Are there any side effects?

Tell your doctor if you notice any of the following and they 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)

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.

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.

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about using TOBI. **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 TOBI.**

Where to find information in this leaflet:

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

1. Why am I using TOBI?

TOBI contains the active ingredient 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 it very young. If the infection is not properly fought, it will continue to damage your lungs, causing further problems with your breathing.

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

For best results, please use TOBI as this leaflet instructs you.

Although TOBI does not cure your condition, it does help control it.

TOBI is not recommended for use in children younger than 6 years of age. Do not give TOBI to a child below the age of 6, unless directed to by the child's doctor or pharmacist.

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

Your doctor may have prescribed TOBI for another reason.

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

2. What should I know before I use TOBI?

Warnings

Do not use TOBI if:

- **you have an allergy to:**
 - TOBI 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.

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

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.

Check with your doctor if you:

- have any other medical conditions
 - 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).
- **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.
- are aged 65 years or older, your doctor may perform additional tests to decide if TOBI is right for you.

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

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.

TOBI may affect your developing baby if you use it during pregnancy. Your doctor or pharmacist will discuss the possible risks and benefits of using TOBI 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 TOBI 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 may interfere with TOBI and affect how it works, 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 TOBI, 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 TOBI.

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

4. How do I use TOBI?

How much to use

Inhale TOBI only when prescribed by your doctor.

Do not exceed the recommended dose.

The recommended dose of TOBI is one 300 mg/5 mL ampoule twice daily (every 12 hours) for 28 days.

This is followed by 28 days of not taking TOBI. 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.

When to use TOBI

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 TOBI LAST.

Use TOBI 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 TOBI twice daily.

Doses should be administered as close to 12 hours apart as possible and not less than 6 hours apart.

How to use TOBI

TOBI 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 De Vilbiss Pulmo-Aide®air compressor or PARI Pro-Neb System reusable nebuliser.

It is important that your nebuliser and compressor function properly before you start your TOBI therapy.

Breathe normally through the mouthpiece of the nebuliser until all of the TOBI 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.

How to inhale TOBI

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 TOBI 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
 - e. 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 TOBI 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 TOBI 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 TOBI

Use TOBI twice daily every day for 28 days, followed by a 28 day period off TOBI. Continue using TOBI 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 TOBI, ask your doctor or pharmacist.

If you forget to use TOBI

If there are at least 6 hours to your next dose, use TOBI 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 TOBI 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 TOBI

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

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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:

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

5. What should I know while using TOBI?

Things you should do

Keep TOBI 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. TOBI is sensitive to very strong light.

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

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

Call your doctor straight away if you:

- become pregnant while using TOBI
- are about to be started on any new medicine
- plan to have surgery that needs a general anaesthetic

Remind any doctor, dentist or pharmacist you visit that you are using TOBI.

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 TOBI which you have stored at room temperature for more than 28 days.**
- **Do not dilute or mix other medications, with TOBI in the nebuliser.**
- **Never use a dirty or clogged nebuliser.**
- **Do not share your nebuliser with other people.**
- **Do not give TOBI to anyone else, even if they have the same condition as you.**
- **Do not use TOBI to treat any other complaints unless your doctor tells you to.**
- **Do not stop using TOBI, 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 TOBI 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 TOBI affects you.

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

If you feel dizzy or light-headed after using TOBI, do not drive.

Make sure you know how you react to TOBI 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.

Drinking alcohol

Tell your doctor if you drink alcohol. If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

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.

Store TOBI between 2-8°C in the refrigerator.

If you do not have a refrigerator available (for example, when you are transporting TOBI), 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 TOBI.

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 TOBI where children cannot reach it.

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

Getting rid of any unwanted medicine

If your doctor tells you to stop using TOBI or the solution has passed its expiry date, ask your pharmacist what to do with any that is left over.

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

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 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. 	<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 hearing loss noises in the ears (such as hissing) dizziness light-headedness clumsiness and lack of coordination 	<p>Tell your doctor immediately.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> chest pain or chest tightness increased coughing, wheezing or difficulty in breathing Generally feeling unwell Discoloration of the substance you cough up (sputum). 	
<ul style="list-style-type: none"> 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 	<p>If you have them, you may have had a serious allergic reaction to TOBI. Tell your doctor immediately or go to accident and emergency at your nearest hospital.</p>

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 TOBI contains

Active ingredient (main ingredient)	Each 5 mL single dose ampoule contains tobramycin 300 mg.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> sodium chloride water for injections nitrogen sulphuric acid# sodium hydroxide# <p># These ingredients may have been added to adjust the pH of the final solution.</p>

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

What TOBI looks like

Each carton of TOBI (AUST R 73172) contains 56 single-dose ampoules (a 28-day supply). The ampoules are in 14 pouches, with 4 ampoules in each pouch.

TOBI is supplied in clear, plastic ampoules that are packaged in foil pouches. The solution is slightly yellow and may darken a little with age, but this does not affect the quality of the

product (as long as it is stored within the recommended storage conditions).

Who distributes TOBI

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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