

# TOBI®PODHALER®

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## 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.

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### 1. Why am I using TOBI PODHALER?

TOBI PODHALER contains the active ingredient tobramycin. TOBI PODHALER is used to treat lung infections caused by a bacterium called *Pseudomonas aeruginosa*, in patients who have cystic fibrosis.

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

### 2. What should I know before I use TOBI PODHALER?

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 TOBI PODHALER?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with TOBI PODHALER 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 PODHALER?

- The usual dose for all patients aged 6 years and older is 4 capsules for inhalation taken every 12 hours (each morning and evening).
- Do not exceed the recommended dose.

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

### 5. What should I know while using TOBI PODHALER?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using TOBI PODHALER.</li></ul>
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	<ul style="list-style-type: none"><li>● Once removed from the blister strip, use the capsule immediately.</li><li>● Use a new PODHALER device after 7 days. Discard the old one.</li><li>● Tell your doctor if you become pregnant while using TOBI PODHALER.</li><li>● Keep all of your doctor's appointments so that your progress can be checked.</li><li>● If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using TOBI PODHALER.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not swallow the capsules. The powder in the capsules are taken by inhalation only, using a PODHALER device that is provided in the pack.</li><li>● Do not use other capsules or powders in the PODHALER device.</li></ul>

	<ul style="list-style-type: none"> <li>• Do not wash the PODHALER device.</li> <li>• Do not change or lower the dosage, without checking with your doctor.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• TOBI PODHALER should not affect your ability to drive and use machines.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store this medicine in a cool, dry place, where the temperature stays below 30°C.</li> </ul>

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

## **6. Are there any side effects?**

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.

# TOBI®PODHALER®

**Active ingredient(s):** *tobramycin*

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## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

## 1. Why am I using TOBI PODHALER?

**TOBI PODHALER contains the active ingredient tobramycin in a powdered form.** TOBI PODHALER is a class of medicines called aminoglycoside antibiotics.

*Pseudomonas aeruginosa* is a very common bacterium that infects the lung of nearly everyone with cystic fibrosis, at some time during their lives. Some people

do not get this infection until later on in their lives, while others get it very young. This infection is one of the most damaging bacteria for people with cystic fibrosis. If it is not properly fought, it will continue to damage your lungs causing further problems to your breathing.

TOBI PODHALER capsules are for oral inhalation only. The powder from the capsule is inhaled (breathed into the lungs), using the TOBI PODHALER inhalation device provided with the medicine. When you inhale the powder, tobramycin gets directly into your lungs, to fight against the *Pseudomonas aeruginosa* bacteria causing the infection.

**TOBIPODHALER is used to treat lung infections caused by a bacterium called pseudomonas aeruginosa, in patients who have cystic fibrosis.**

TOBI PODHALER is only available with a doctor's prescription. It is not addictive. This medicine can be used in children aged 6 years or over, adolescents, and adults.

## **2. What should I know before I use TOBI PODHALER?**

### **Warnings**

#### **Do not use TOBI PODHALER if:**

- you are allergic to tobramycin, any type of aminoglycoside antibiotic, or any of the ingredients listed at the end of this leaflet. See symptoms of an

allergic reaction under Section [6. Are there any side effects?](#).

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

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

### **Check with your doctor if you:**

- have allergies to any other medicines or any other substances, such as foods, preservatives or dyes. See symptoms of an allergic reaction under Section [6. Are there any side effects?](#).
- aged 65 years or older, your doctor may perform additional tests to decide if TOBI PODHALER is right for you. Your doctor will supervise your first dose of this medicine and check your lung function before and after dosing.
- are taking any other medicines
- have hearing problems (including noises in the ears and dizziness)
- have Kidney problems
- have unusual difficulty in breathing with wheezing or coughing, chest tightness
- blood in your sputum (the substance you cough up)
- have muscle weakness that lasts or becomes worse in time, a symptom mostly related to conditions such as myasthenia or Parkinson's disease.

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 PODHALER 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 PODHALER 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 PODHALER 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 TOBI PODHALER and affect how it works.**



- diuretics (fluid tablets), especially those that contain furosemide, etacrynic acid, urea or intravenous mannitol
- tobramycin or another aminoglycoside antibiotic by injection (eg. amikacin, gentamicin, neomycin, streptomycin)

**Medicines that may increase the effect of TOBI PODHALER include:**

- Amphotericin B (an antifungal medicine)
- Cefalotin or polymyxins (antibiotic medicines)
- Ciclosporin or tacrolimus (medicines that help to control your body's immune system)
- Carboplatin, cisplatin, or other platinum compounds (usually used in the treatment of various cancer types)
- Anticholinesterase medicines, such as neostigmine and pyridostigmine
- Botulinum toxin (a medicine used to relax muscles)

**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 PODHALER.**

## **4. How do I use TOBI PODHALER?**

### **How much to use**

- The usual dose for all patients aged 6 years and older is 4 capsules for inhalation taken every 12 hours (each morning and evening).
- Do not exceed the recommended dose.

- Follow the instructions provided when TOBI PODHALER was prescribed, including the number of days it should be taken.
- Always use TOBI PODHALER exactly as your doctor has told you.
- Your doctor may ask you to use other medicines before using TOBI PODHALER.
- You should check with your doctor if you are not sure.
- Children 6 years and over should use this medicine with the help of an adult.
- When initiating children on PODHALER treatment, caregivers should particularly provide assistance to those aged 10 years or younger, and should continue to supervise them until they are able to use the PODHALER inhaler properly without help. If you are not sure how to use the medicine and PODHALER device, which are provided in the pack, ask your doctor or pharmacist.

## **When to use TOBI PODHALER**

- TOBI PODHALER should be used twice a day (morning and evening) at about the same time each day. You must leave as close as possible to 12 hours between doses.
- Using your medicine at the same time each day will help you remember when to take it. TOBI PODHALER is taken in a 28 day cycle.
- After taking the medicine for 28 days, you will have a 28-day break, during which you do not inhale any TOBI PODHALER. You then start another course.

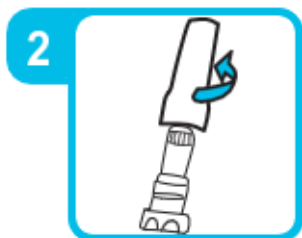
- Please check the order of medications with your doctor.
- If you are taking several different inhaled treatments and performing therapies for cystic fibrosis, you should use TOBI PODHALER last.

## How to use TOBI PODHALER

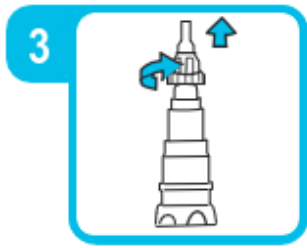
USE A NEW PODHALER INHALATION DEVICE EVERY WEEK



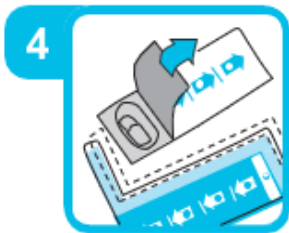
Wash and fully dry hands.



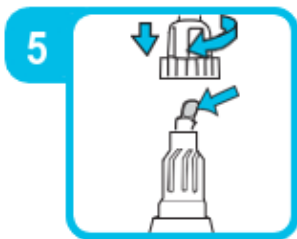
Just before use, remove the PODHALER device from its case by holding the base and twisting off the top of the case in a counter-clockwise direction. Set the top of the case aside. Briefly inspect the inhaler to make sure it is not damaged or dirty, and then stand it in the base of the case.



Holding the body of the inhaler, unscrew and remove the mouth piece from the inhaler body. Set the mouth piece aside on a clean, dry surface.



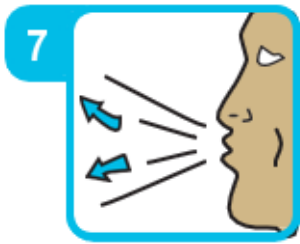
Separate the morning and evening doses from the capsule card. Peel back the foil from the capsule card to reveal one capsule and remove it from the card.



Immediately insert the capsule into the inhaler chamber. Replace the mouth piece and screw it on firmly until it stops. Do not over tighten.



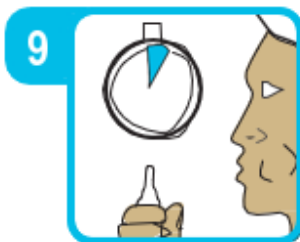
The medication is now ready for inhalation.



Fully exhale away from the inhaler.



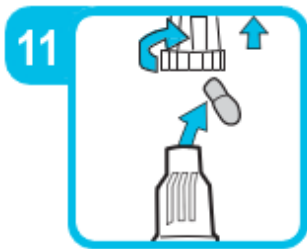
Position the inhaler with the mouth piece facing towards you. Place mouth over the mouth piece creating a tight seal. Inhale the powder deeply with a single continuous inhalation.



Remove inhaler from mouth, and hold breath for a count of approximately 5 seconds then exhale normally away from the inhaler.



After a few normal breaths, perform a second inhalation from the same capsule, repeating steps 7, 8 and 9.



Unscrew mouth piece and remove the capsule from the chamber. Inspect the used capsule. It should appear punctured and empty .

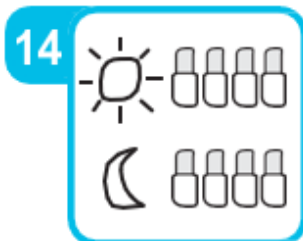


If the capsule is punctured but still contains some powder, place it back into the chamber with the punctured side of the capsule inserted first, replace the mouth piece and take another two inhalations from the capsule (repeat step 5, then steps 7 to 11). Reinspect capsule.



If the capsule appears to be unpunctured, place it back into the chamber, replace the mouth piece, press the button firmly as far as it goes and take another two inhalations from the capsule (repeat steps 5 to 11). If

the capsule is still full and appears to be unpunctured, replace the inhaler with the reserve inhaler and try again (repeat steps 2, 3, and 5 to 11). Discard the empty capsule.



Repeat, starting at step 4, for the remaining 3 capsules of the dose.



Replace the mouth piece and screw it on firmly until it stops. When the full dose (4 capsules) has been inhaled, wipe the mouthpiece with a clean, dry cloth.



Place inhaler back in storage case and close tightly. The inhaler should never be washed with water.



**Continue to take TOBI PODHALER, in the cycling pattern, for as long as your doctor tells you.**

It is important that you keep using the product twice each day during your 28 days on treatment and that you keep to the 28-day on and 28-day off cycle. Continue to take TOBI, in the cycling pattern, for as long as your doctor tells you.

## **If you forget to use TOBI PODHALER**

TOBI PODHALER should be used twice a day (morning and evening) at about the same time each day. You must leave as close as possible to 12 hours between doses. If you miss your dose at the usual time, take your dose as soon as you remember if there are at least 6 hours to your next dose. 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 an unwanted side effect.



- Use your medicine at the same time each day. This will help you remember to take your medicine dose.
- If you have trouble remembering when to use your medicine, ask your doctor or pharmacist for some hints.

## **If you use too much TOBI PODHALER**

If you think that you have used too much TOBI PODHALER, 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.**

If you use too much of this medicine, you may feel:

- dizziness
- ringing in the ears
- loss of hearing
- difficulty or decreased breathing
- weakness

## **5. What should I know while using TOBI PODHALER?**

### **Things you should do**

- Once removed from the blister strip, use the capsule immediately.
- Avoid using the product in a very humid environment, for example in tropical regions or in bathrooms.
- Use a new PODHALER device after 7 days. Discard the old one.
- Keep all of your doctor's appointments so that your progress can be checked. Over time, strains of *Pseudomonas* can become resistant to the treatment of an antibiotic. This may mean that TOBI PODHALER may not work as well as it should over time.

### **Call your doctor straight away if you:**

- become pregnant.
- are about to be started on any new medicine.
- experience a persistent cough and it is worrying you. Inhaling medicines can also cause cough and this may happen when using this medicine. Inhaling medicines can cause chest tightness and wheezing. This may happen immediately after inhaling this medicine.
- 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.

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

## **Things you should not do**

- Do not swallow the capsules. The powder in the capsules are taken by inhalation only, using a Podhaler device that is provided in the pack. If you have swallowed the capsules in error, tell your doctor as soon as possible. When swallowed, the capsules will not harm you, but this medicine will not work against your lung infection, as it is meant to.
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use other capsules or powders in the Podhaler device.
- Do not wash the Podhaler device.
- Do not change or lower the dosage, without checking with your doctor.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how TOBI PODHALER affects you.**

TOBI PODHALER should not affect your ability to drive and use machines.

## **Looking after your medicine**

Clean the Podhaler after each use by wiping it with a clean dry cloth or tissue.

It is important to keep your Podhaler clean and dry. It may not work as well if it gets dirty or wet.

Keep your medicine in the original container until it is time to use it.

Keep the Podhaler in its tightly closed case when not in use.

Follow the instructions in the carton on how to take care of your medicine properly.

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.**

## **When to discard your medicine**

**Discard your medicine when your doctor stops your treatment with TOBI PODHALER or you find that it has passed the expiry date.**

## **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**

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Respiratory system:</b></p> <ul style="list-style-type: none"><li>• Shortness of breath</li><li>• Cough or a productive cough</li><li>• Voice alteration (hoarseness)</li><li>• Loss of your voice</li><li>• Sore throat</li><li>• Headache</li><li>• Fever</li><li>• Wheezing, crackles</li><li>• Chest discomfort, chest pain from muscles and/or skeleton origins</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Decreased results for the tests of lung function</li> <li>● High level of sugar (glucose) in the blood</li> <li>● Blocked nose</li> <li>● Nosebleed</li> <li>● Vomiting, nausea</li> <li>● Diarrhoea</li> <li>● Rash</li> <li>● Disturbed sense of taste</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● Unusual difficulty in breathing, with wheezing or coughing or chest tightness</li> <li>● Worsening of your underlying lung disease</li> <li>● Coughing up blood</li> <li>● Decreasing hearing (ringing in the ears is a potential warning sign of hearing loss)</li> <li>● Noises (such as hissing) in the ears</li> </ul>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Generally feeling unwell</li> <li>• Discoloration of the substance you cough up (sputum)</li> </ul>	

## **Allergic reactions**

<ul style="list-style-type: none"> <li>• <b>Severe rash, itching or hives on the skin</b></li> <li>• <b>Swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing, or swelling of any other parts of the body</b></li> <li>• <b>Fast heart beat, dizziness, vertigo, unsteadiness, and light headedness</b></li> <li>• <b>Wheezing or shortness of breath</b></li> </ul>	<p><b>Tell your doctor or pharmacist asap if you notice anything that is making you feel unwell.</b></p>
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**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](http://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 PODHALER contains

<b>Active ingredient (main ingredient)</b>	Tobramycin
<b>Other ingredients (inactive ingredients)</b>	Distearoylphosphatidylcholine Calcium chloride dihydrate Sulfuric acid (for pH adjustment) The capsule shell contains:



	Hypromellose (E464) Potassium chloride (E508) Carrageenan (E407) Carnauba wax (E903) Indigo carmine aluminium lake Isopropyl alcohol Propylene glycol Purified water Shellac Titanium dioxide
<b>Potential allergens</b>	Soya bean products

Each hard capsule contains tobramycin 28 mg inhalation powder.

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

### **What TOBI PODHALER looks like**

TOBI PODHALER is Clear, colourless capsules, containing a white to almost white powder. The capsules have "MYL TPH" in blue radial imprinted on one part of the capsule, and the Mylan logo in blue radial imprinted on the other part of the capsule.

Each sealed foil pack contains a capsule card. The card contains a daily dose of 8 capsules (combined morning and evening doses).

A carton contains 224 capsules and 5 plastic podhaler devices (AUST R 182302).

The capsules must be administered specifically with a Podhaler® device provided in the same pack.

## **Who distributes TOBI PODHALER**

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatrix.com.au](http://www.viatrix.com.au)

Phone: 1800 274 276

TOBI® and Podhaler® are a Viatrix company trade mark.

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**TOBI PODHALER\_cmi\Aug24/00**