

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrTOBI® PODHALER® Tobramycin Inhalation Powder Capsules

Read this carefully before you start taking **TOBI PODHALER** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TOBI PODHALER**.

What is TOBI PODHALER used for?

TOBI PODHALER is used to treat people (six years and older) with cystic fibrosis who have a bacterial lung infection with *Pseudomonas aeruginosa* (see “What is *Pseudomonas aeruginosa*?” section below).

Antibacterial drugs like TOBI PODHALER treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, TOBI PODHALER should be used exactly as directed. Misuse or overuse of TOBI PODHALER could lead to the growth of bacteria that will not be killed by TOBI PODHALER (resistance). This means that TOBI PODHALER may not work for you in the future. Do not share your medicine.

How does TOBI PODHALER work?

TOBI PODHALER contains a medicine called tobramycin. Tobramycin belongs to the aminoglycoside class of antibiotics. TOBI PODHALER is inhaled (breathe) directly into the lungs so that the antibiotic can kill the *Pseudomonas aeruginosa* bacteria causing the infection. This helps to fight lung infections and improve breathing in people with cystic fibrosis.

What is Pseudomonas aeruginosa?

It 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. It is one of the most damaging bacteria for people with cystic fibrosis. If the infection is not properly fought, it will continue to damage your lungs causing further problems to your breathing.

What are the ingredients in TOBI PODHALER?

Medicinal ingredients: Tobramycin

Non-medicinal ingredients: 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), blue ink, calcium chloride, carnauba wax, carrageenan, hypromellose, potassium chloride, sulfuric acid (for pH adjustment)

TOBI PODHALER comes in the following dosage forms:

28 mg inhalation powder capsules

Do not use TOBI PODHALER if you are allergic:

- to tobramycin, or to any other aminoglycoside antibiotic such as amikacin,

- gentamycin, kanamycin, paromomycin, streptomycin, to any of the other ingredients in TOBI PODHALER (see What are the ingredients in TOBI PODHALER?).

If this applies to you, **tell your healthcare professional without taking TOBI PODHALER**. If you think you may be allergic, ask your healthcare professional for advice.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TOBI PODHALER. Talk about any health conditions or problems you may have, including if:

- You have hearing problems (including noises in the ears).
- You have vestibular problems (problems with your inner ear and brain) that can cause vertigo (loss of balance) and dizziness.
- You have kidney problems.
- You have unusual difficulty in breathing with wheezing or coughing and chest tightness.
- You have blood in your sputum (the substance you cough up).
- You have Parkinson's disease.
- You have a condition called myasthenia gravis which is a chronic disease that causes muscle weakness.
- You are breastfeeding or planning to breastfeed.
- You are receiving an antibiotic called an aminoglycoside by injection since this can cause hearing loss, kidney problems or dizziness.
- You are taking any other medicines.

Other warnings you should know about:

Pregnancy:

Before taking TOBI PODHALER, talk to your healthcare professional if you are pregnant or want to become pregnant. It is not known whether inhaling this medicine can harm an unborn baby. When given by injection, the medicine in TOBI PODHALER can harm an unborn baby and cause deafness. Your healthcare professional will talk to you about whether you can take TOBI PODHALER if you are pregnant.

Breastfeeding:

When given by injection, the medicine in TOBI PODHALER can be found in the breast milk. The quantity found in the breast milk after inhaling TOBI PODHALER is not known. TOBI PODHALER may cause problems to your baby's hearing or kidneys. Because of the importance of the medicine to your well-being, you should stop breastfeeding or stop taking TOBI PODHALER.

TOBI PODHALER is in a class of antibiotics that may cause hearing loss, dizziness, or kidney problems. While you are using TOBI PODHALER and if you have or are at risk of hearing or kidney problems, your healthcare professional may do bloodwork to check how your kidneys are working. You may also take a hearing test to check whether or not TOBI PODHALER is affecting your hearing.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with TOBI PODHALER:

You should not take the following medicines while you are taking TOBI PODHALER:

- Furosemide or ethacrynic acid, a diuretic (“water pills”)
- Urea or intravenous mannitol

You should not take the following medicines while you are taking TOBI PODHALER, or soon after finishing TOBI PODHALER treatment:

- Medicines (including tobramycin or another aminoglycoside antibiotic given by injection) that may harm your nervous system, kidneys or hearing. This interaction may cause hearing loss, dizziness, or kidney problems.

The following medicines can increase the chances of harmful effects occurring if they are given to you while you are receiving infusions of tobramycin or other aminoglycoside antibiotic. Talk with your healthcare professional before taking these medications:

- Amphotericin B, cefalotin, cyclosporine, tacrolimus, polymyxins: these medicines may harm your kidneys.
- Platinum compounds (such as carboplatin and cisplatin): these medicines may harm your kidneys or hearing.
- Anticholinesterases, (such as neostigmine and pyridostigmine), or botulinum toxin: these medicines may cause muscle weakness to appear or become worse.

Many other medications may also harm your nervous system, kidneys or hearing. Tell your healthcare professional about all the medications you are taking, even those that do not appear on this list.

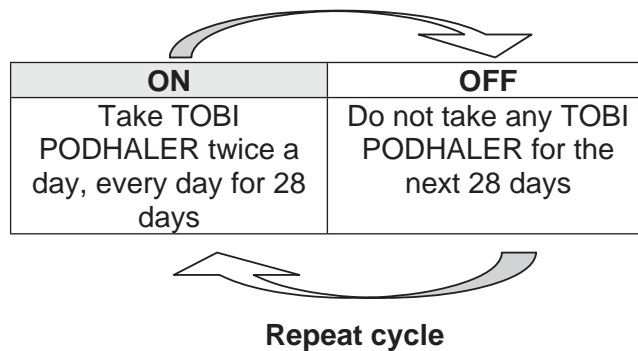
How to take TOBI PODHALER:

- TOBI PODHALER is a powder specifically formulated for inhalation using the PODHALER inhaler (see the step-by-step Instructions in the “**How To Administer TOBI PODHALER**” section below),
- Take TOBI PODHALER exactly as your healthcare professional tells you to. Ask your healthcare professional if you are not sure.
 - Do not swallow the capsules.
 - TOBI PODHALER capsules should be taken by inhalation using only the PODHALER that is provided in the pack.
 - Each PODHALER is used for seven days and then discarded and replaced.
 - No other capsules should be used with the PODHALER.
- Take TOBI PODHALER at the same time each day. This will help you remember when to take TOBI.
- Space the morning and evening doses as close as possible to 12 hours and not less than 6 hours apart.
- Please check the order of medications with your doctor. If you are taking several medications and have other therapies for cystic fibrosis, TOBI PODHALER should always be taken last. Take your medicines in the following order :
 - 1st bronchodilator

- 2nd chest physiotherapy
- 3rd other inhaled medications
- 4th TOBI PODHALER
- Continue taking TOBI PODHALER as your healthcare professional tells you.
- If you have questions about how long to take TOBI PODHALER, talk to your doctor or your pharmacist.

Usual dose:

- Usual dose of TOBI PODHALER in adults and children 6 years of age and older:
 - Inhale the content of 4 capsules (with 112 milligrams (mg) of tobramycin) in the morning and 4 capsules in the evening for 28 days using the PODHALER.
- After taking TOBI PODHALER for 28 days, stop using it and wait 28 days before starting another 28-days treatment cycle again.
- It is important that you keep using TOBI PODHALER two times per day during your 28 days on treatment and that you keep to the 28-day on, 28-day off cycle (see picture below).



Overdose:

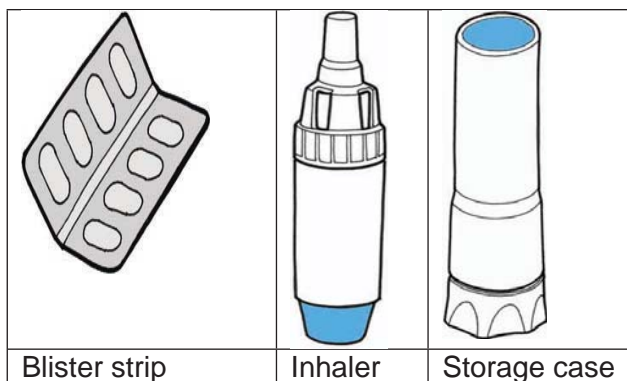
If you think you have taken too much TOBI PODHALER, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you forget to take TOBI PODHALER and there are at least 6 hours to your next dose, take your dose as soon as you can. Otherwise, wait for your next dose.
- Do not take a double dose to make up for a missed dose.


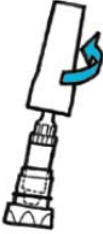

Contents of the TOBI PODHALER Inhaler pack:

Each weekly box contains seven blister strips (corresponding to the seven days of the week) and each blister strip contains eight capsules (corresponding to a daily dose: content of 4 capsules to be inhaled in the morning and content of 4 capsules to be inhaled in the evening).

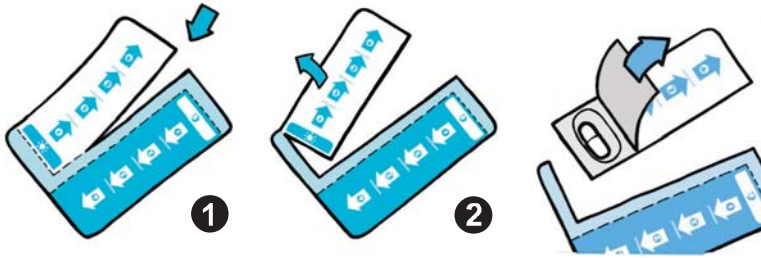


How to administer TOBI PODHALER:

This information is not intended to replace consultation with your healthcare professional, and cystic fibrosis care team about properly taking medication or using inhalation equipment.

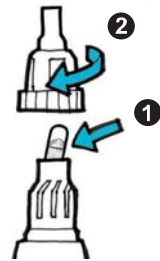
TOBI PODHALER Preparation	
1. Wash and fully dry your hands.	
<p><i>Allow the device and capsules to reach room temperature before use.</i></p> 2. Just before use, remove the PODHALER from its case by holding the base and twisting off the top of the case in a counter-clockwise direction.	
<p><i>Set the top of the case aside. Briefly inspect the inhaler to make sure it is not damaged or dirty, then stand it in the base of the case.</i></p> 3. Holding the body of the inhaler, unscrew and remove the mouthpiece from the inhaler body. Set the mouthpiece aside on a clean, dry surface.	
4. Separate the morning and evening doses from the blister strip as indicated in pictures (1) and (2). Peel back the foil from the blister strip to reveal one TOBI PODHALER	

capsule and remove it from the card.



Always keep the TOBI PODHALER capsules in the blister strip. Only remove a capsule just before you are going to use it. Do not store the capsules in the inhaler.

5. Immediately insert the capsule into the inhaler chamber (1). **Never place a TOBI PODHALER capsule directly into the mouthpiece of the device.** Replace the mouthpiece and screw it on firmly until it stops (2). **Do not overtighten.**



6. To puncture capsule, hold the inhaler with the mouthpiece down, press the blue button firmly with your thumb as far as it will go, then release the button. **Do not press the piercing button more than once at a time.** The medication is now ready for inhalation.




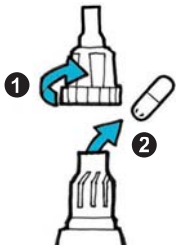
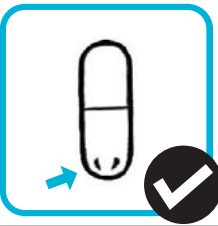
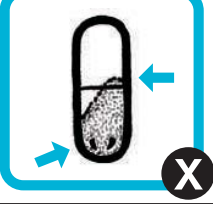
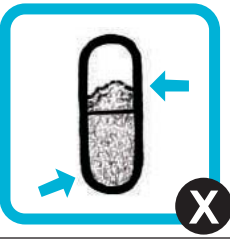
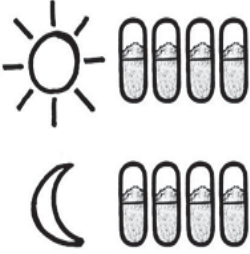
Occasionally, very small pieces of the capsule can get past the screen and get into your mouth.


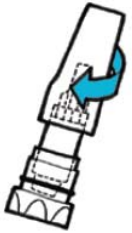
- *If this happens, you may be able to feel these pieces on your tongue.*
- *It is not harmful if these pieces are swallowed or inhaled.*
- *The chances of the capsule breaking into pieces will be increased if the capsule is accidentally pierced more than once during step 6.*

TOBI PODHALER Inhalation

7. Fully exhale away from the inhaler. **Never blow into the mouthpiece of the device.** Position the inhaler with the mouthpiece facing towards you. Place mouth over the mouthpiece 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.



<p>8. After a few normal breaths, perform a second inhalation from the same capsule, repeating step 7 above.</p>	
<p>Check and Continue</p>	
<p>9. Unscrew mouthpiece (1) and remove the capsule from the chamber (2).</p>	
<p>10. Inspect the used capsule. It should appear punctured and empty. If it is empty, discard the capsule.</p>	
<p><i>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 mouthpiece and take another two inhalations from the capsule (repeat step 5, then steps 7 to 10 – do not repuncture the capsule). Reinspect capsule.</i></p>	
<p><i>If the capsule appears to be unpunctured, place it back into the chamber, replace the mouthpiece, press the button firmly as far as it goes and take another two inhalations from the capsule (repeat steps 5 to 10). After this if the capsule is still full and appears to be unpunctured, replace the inhaler with the reserve inhaler and try again (repeat steps 3, and 5 to 10).</i></p>	
<p>11. Repeat, starting at step 4 , for the remaining three capsules of the dose.</p>	

<p>12. Replace the mouthpiece and screw it on firmly until it stops. When the full dose (4 capsules) has been inhaled, wipe mouthpiece with a clean dry cloth.</p> <p><i>The inhaler should never be washed with water.</i></p>	
<p>13. Place inhaler back in storage case and close tightly.</p>	
<p><i>Always keep the TOBI PODHALER capsules and device in a dry place</i></p>	

Older people

If you are aged 65 years and older, your healthcare professional may perform additional tests to decide if TOBI PODHALER is right for you.

Children and adolescents

Caregivers should provide assistance to children starting TOBI PODHALER treatment, particularly those aged 10 years or younger, and should continue to supervise them until they are able to use the PODHALER device properly without help.

TOBI PODHALER can be taken by children and adolescents aged 6 years and older. TOBI PODHALER should not be given to children less than 6 years old.

Driving and using machines

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

What are possible side effects from using TOBI PODHALER?

These are not all the possible side effects you may feel when taking TOBI PODHALER. If you experience any side effects not listed here, contact your healthcare professional.

Some side effects are very common (these side effects may affect more than 1 in 10 patients):

- Cough.
- Difficulty speaking.

Some side effects are common (these side effects may affect between 1 and 10 in every 100 patients):

- Difficult or laboured breathing.
- Change in sense of taste.
- Mouth pain.
- Sore throat.

Some side effects are uncommon (these side effects may affect between 1 and 10 in every 1000 patients):

- Loss of voice (aphonia)

The frequency of some side effects is not known (the frequency cannot be estimated from the available data):

- Change in the colour of your sputum (substance you cough up).
- General feeling of being unwell.

If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have *Clostridium difficile* colitis (bowel inflammation). If this occurs, stop taking TOBI PODHALER and contact your healthcare professional immediately.

Talk to your healthcare professional if the following occurs while taking TOBI PODHALER

- If you are not getting better. Strains of *Pseudomonas* can become resistant to treatment with the antibiotic over time. This can mean TOBI PODHALER may not work as well over time.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Worsening of your underlying lung disease		X	
COMMON			
Unusual difficulty in breathing with wheezing or coughing and chest tightness (bronchospasm)			X
Coughing up blood		X	
Hearing problems: <ul style="list-style-type: none"> • ringing in the ears (is a potential warning sign of hearing loss) • noises (such as hissing) in the ears • any changes in hearing 			X
Shortness of breath, productive cough, sore throat, headache, fever	X		
Wheezing, rales (crackles), chest discomfort, chest pain from muscles and/or skeleton origins, decreased results for the tests of lung function, high level of sugar (glucose) in the	X		

blood			
NOT KNOWN			
Allergic reactions: <ul style="list-style-type: none"> • skin rash • hives • itching • difficulty breathing • throat tightness • facial swelling • flushing (warmth and redness of the skin) 			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store TOBI PODHALER capsules between 15-30°C.
- Store TOBI PODHALER capsules in the original package to protect from moisture.
- Store the inhaler in its tightly closed case when not in use.
- Do not use TOBI PODHALER beyond the expiration date stamped on the box.
- Keep out of reach and sight of children.

If you want more information about TOBI PODHALER:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website www.mylan.ca, or by calling 1-844-596-9526.

This leaflet was prepared by
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Last Revised January-10-2022