

TOBI® PODHALER®

tobramycin capsules for inhalation

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TOBI Podhaler capsules for inhalation.

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. You can also download the most up to date leaflet from www.novartis.com.au (for Australia)

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TOBI Podhaler against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What TOBI Podhaler is used for

TOBI Podhaler capsules for inhalation contain a medicine called tobramycin in a powdered form. Tobramycin belongs to a class of

medicines called aminoglycoside antibiotics.

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

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.

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

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.

Before you use TOBI Podhaler

When you must not use it

Do not use TOBI Podhaler if you have an allergy to:

- tobramycin (the active ingredient in TOBI Podhaler)
- any type of aminoglycoside antibiotic
- any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin.

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

Do not use TOBI Podhaler after the expiry date printed on the pack or if the packaging is torn or if it shows signs of tampering

In that case, return it to your pharmacist.

Do not give this medicine to a child under the age of 6 years.

If you are not sure whether you or your child should start using TOBI Podhaler, contact your doctor or pharmacist.

Before you start to use it

Tell your doctor if you are allergic to any other medicines, foods, dyes, or preservatives.

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 TOBI Podhaler is right for you.

Tell your doctor if you have any of the following medical conditions:

- hearing problems (including noises in the ears and dizziness)
- kidney problems
- unusual difficulty in breathing with wheezing or coughing, chest tightness
- blood in your sputum (the substance you cough up)
- muscle weakness that lasts or becomes worse in time, a symptom mostly related to conditions such as myasthenia or Parkinson's disease.

Your doctor may want to take extra precautions in that case.

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

It is not known whether inhaling this medicine during pregnancy could affect your baby. Your doctor will discuss the possible risks and benefits with you.

Talk to your doctor if you are breastfeeding or plan to breast feed.

It is not known whether the active ingredient passes into the breast milk and may affect your baby.

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

Your doctor will supervise your first dose of this medicine and check your lung function before and after dosing.

Using 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.

It is possible that some medicines and TOBI Podhaler could interfere with each other. These include:

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

Your doctor or pharmacist can advise you.

Some medicines, when used with TOBI Podhaler, may increase the chances of side effects occurring. These medicines include:

- Amphotericin B (an antifungal medicine)
- Cefalotin or polymyxins (antibiotic medicines)
- Cyclosporin 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 different cancer types)
- Anticholinesterase medicines, such as neostigmine and pyridostigmine
- Botulinum toxin (a medicine used to relax muscles)

You may need to take different amounts of these medicines or you may need to take different medicines. Your doctor or pharmacist have more information and will advise you.

If you have not told your doctor about any of these things, tell him/her before you use TOBI Podhaler.

How to use TOBI Podhaler

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Children 6 years and over should use this medicine with the help of an adult.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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.

When to use TOBI Podhaler

Use this medicine 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 it

Each pack of this medicine contains an instruction leaflet that tells you the correct way to use it. Read it carefully.

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.

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.

How to use TOBI Podhaler

1. Wash and fully dry hands.
2. 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.
3. 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.
4. 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.
5. Immediately insert the capsule into the inhaler chamber. Replace the mouth piece and screw it on firmly until it stops. Do not over tighten.
6. To puncture the capsule, hold the inhaler with the mouth piece down, press the button firmly with your thumb as far as it will go, then release the button.

The medication is now ready for inhalation.

7. Fully exhale away from the inhaler.
8. 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.
9. Remove inhaler from mouth, and hold breath for a count of approximately 5 seconds, then exhale normally away from the inhaler.
10. After a few normal breaths, perform a second inhalation from the same capsule, repeating steps 7, 8 and 9.
11. Unscrew mouth piece and remove the capsule from the chamber. Inspect the used capsule.
It should appear punctured and empty.
12. 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.
13. 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.
14. Repeat, starting at step 4, for the remaining 3 capsules of the dose.
15. 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.

16. Place inhaler back in storage case and close tightly.

The inhaler should never be washed with water.

How long to use it

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.

Follow your doctor's instructions carefully.

If you forget to use it

If there are at least 6 hours to your next dose, take your dose as soon as you remember. Then go back to using your medicine as you would normally.

Otherwise, if it is almost time for your next dose, skip the dose you missed and use the next dose when you are meant to.

If you are not sure what to do, ask your doctor or pharmacist.

Do not use a double dose to make up for the dose that 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 (Overdose)

Immediately telephone your doctor or the Poisons Information Centre telephone number: 13 11 26 for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have used too much medicine.

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

You may need urgent medical attention.

Keep the telephone numbers for these places handy.

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

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

While you are using TOBI Podhaler

Things you must do

Once removed from the blister strip, use the capsule immediately. You should 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.

Tell your doctor if you become pregnant while using TOBI Podhaler.

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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using TOBI Podhaler.

Tell any other doctor, dentist or pharmacist who treats you that you are using TOBI Podhaler.

Things you must 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.

Things to be careful of

Inhaling medicines can cause chest tightness and wheezing. This may happen immediately after inhaling this medicine.

Talk to your doctor if you experience a persistent cough and it is worrying you.

Inhaling medicines can also cause a cough and this may happen when using this medicine.

Talk to your doctor if you are concerned about this.

This medicine should not affect your ability to drive and use machines.

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.

Side effects

Tell your doctor or pharmacist if you notice anything that is making you feel unwell while you are using this medicine.

All medicines can have side effects, although not everyone gets them. Sometimes they are serious, but 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 side effects and they worry you:

- shortness of breath
- cough or a productive cough
- voice alteration (hoarseness)
- loss of your voice
- sore throat
- headache
- fever
- wheezing, 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 blood
- blocked nose
- nosebleed
- vomiting, nausea
- diarrhoea
- rash
- disturbed sense of taste

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

- unusual difficulty in breathing with wheezing or coughing or chest tightness
- worsening of your underlying lung disease
- coughing up blood
- decreased hearing (ringing in the ears is a potential warning sign of hearing loss)
- noises (such as hissing) in the ears
- generally feeling unwell
- discoloration of the substance you cough up (sputum).

These may be serious side effects. You may need urgent medical attention. Most serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice

any signs of an allergic reaction to TOBI Podhaler.

Symptoms of an allergic reaction may include:

- severe rash, itching or hives on the skin
- swelling of the face, lips, tongue which may cause difficulty in swallowing or breathing, or swelling of any other parts of the body
- fast heartbeat, dizziness, vertigo, unsteadiness and light headedness
- wheezing or shortness of breath

Tell your doctor or pharmacist as soon as possible if you notice anything else that is making you feel unwell.

Other side effects not listed here may occur in some people.

After using TOBI Podhaler

Cleaning

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.

Store this medicine in a cool, dry place, where the temperature stays below 30°C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep the medicine 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.

Disposal

If your doctor stops your treatment with TOBI Podhaler or you find that it has passed the expiry date, ask your pharmacist what to do with any medicine you have left over.

Medicines should not be disposed via wastewater or household waste. These measures will help to protect the environment.

Product description

What it looks like

Clear, colourless capsules, containing a white to almost white powder. The capsules are coded with "NVR AVCI", imprinted in blue ink on one part of the capsule, and the Novartis logo imprinted in blue 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.

Ingredients

Active Ingredient

Each hard capsule contains tobramycin 28 mg inhalation powder.

Inactive ingredients

The powder for inhalation also contains:

- distearoylphosphatidylcholine
- calcium chloride
- sulfuric acid (for pH adjustment)

The capsule shell contains:

- Hypromellose (E464)
- Potassium chloride (E508)
- Carrageenan (E407)
- Carnauba wax (E903)
- Edible blue ink

This medicine does not contain gelatin, sucrose, lactose, mannitol, or tartrazine.

Sponsor

TOBI Podhaler is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
North Ryde NSW 2113
Telephone 1800 671 203

®= Registered Trademark

Australian Registration Number:
AUST R 182302

This leaflet was prepared in June 2015.

(tip040119c.doc) based on PI
(tob040119i.doc)