

## Package leaflet: Information for the user

### TOBI Podhaler 28 mg inhalation powder, hard capsules tobramycin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What TOBI Podhaler is and what it is used for
2. What you need to know before you take TOBI Podhaler
3. How to take TOBI Podhaler
4. Possible side effects
5. How to store TOBI Podhaler
6. Contents of the pack and other information  
Instructions for use with the Podhaler device (*overleaf*)

#### 1. What TOBI Podhaler is and what it is used for

##### What TOBI Podhaler is

TOBI Podhaler contains a medicine called tobramycin which is an antibiotic. This antibiotic belongs to a class called aminoglycosides.

##### What TOBI Podhaler is used for

TOBI Podhaler is used in patients aged 6 years and older who have cystic fibrosis to treat lung infections caused by bacteria called *Pseudomonas aeruginosa*.

For the best results from this medicine, please use it as this leaflet instructs you.

##### How TOBI Podhaler works

TOBI Podhaler is a powder for inhalation that is filled into capsules. When you inhale TOBI Podhaler, the antibiotic can enter directly into your lungs to fight against the bacteria causing the infection and to improve your breathing.

##### What is *Pseudomonas aeruginosa*

It is a very common bacterium that infects the lungs 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.

#### 2. What you need to know before you take TOBI Podhaler

##### Do not take TOBI Podhaler

- **if you are allergic** to tobramycin, to any type of aminoglycoside antibiotic, or to any of the other ingredients of this medicine (listed in section 6).

If this applies to you, **tell your doctor without taking TOBI Podhaler.**

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

## Warnings and precautions

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

- hearing problems (including noises in the ears and dizziness), or your mother has had hearing problems after taking an aminoglycoside
- certain gene variants (a change in the gene) related to hearing abnormalities inherited from your mother
- 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 over time, a symptom mostly related to conditions such as myasthenia or Parkinson's disease.

If any of these apply to you, **tell your doctor before taking TOBI Podhaler.**

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

Inhaling medicines can cause chest tightness and wheezing and this can happen immediately after inhalation of TOBI Podhaler. Your doctor will supervise your first dose of TOBI Podhaler and check your lung function before and after dosing. Your doctor may ask you to use other appropriate medicines before taking TOBI Podhaler.

Inhaling medicines can also cause cough and this can happen with TOBI Podhaler. Talk to your doctor if the cough is persistent and is a burden for you.

Strains of *Pseudomonas* can become resistant to treatment with an antibiotic over time. This means that TOBI Podhaler may not work as well as it should over time. Talk to your doctor if you are concerned about this.

If you are taking tobramycin or another aminoglycoside antibiotic by injection, it can sometimes cause hearing loss, dizziness and kidney damage.

## Children

TOBI Podhaler should not be given to children less than 6 years old.

## Other medicines and TOBI Podhaler

Tell your doctor or a pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

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

- Furosemide or ethacrynic acid, diuretics
- Other medicines with diuretic properties such as urea or intravenous mannitol
- Other medicines which may harm your kidneys or hearing.

The following medicines can increase the chances of harmful effects occurring if they are given to you while you are also receiving **injections** of tobramycin or other aminoglycoside antibiotic:

- Amphotericin B, cefalotin, polymyxins (used to treat microbial infections), ciclosporin, tacrolimus (used to reduce the activity of immune system). These medicines may harm the kidneys.
- Platinum compounds such as carboplatin and cisplatin (used to treat some forms of cancer). These medicines may harm the kidneys or hearing.
- Anticholinesterases such as neostigmine and pyridostigmine (used to treat muscle weakness), or botulinum toxin. These medicines may cause muscle weakness to appear or become worse..

If you are taking one or more of the above medicines, discuss with your doctor before you take TOBI Podhaler.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

It is not known whether inhaling this medicine when you are pregnant causes side effects.

When they are given by an injection, tobramycin and other aminoglycoside antibiotics can cause harm to an unborn child, such as deafness.

If you are breast feeding, you should talk to your doctor before taking this medicine.

**Driving and using machines**

TOBI Podhaler has no or negligible influence on the ability to drive and use machines.

**3. How to take TOBI Podhaler**

Always take TOBI Podhaler exactly as your doctor has told you. You should check with your doctor if you are not sure.

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.

**How much TOBI Podhaler to take**

Inhale the content of 4 capsules twice a day (4 capsules in the morning and 4 capsules in the evening), using the Podhaler device.

The dose is the same for everyone aged 6 years and older. Do not exceed the recommended dose.

**When to take TOBI Podhaler**

Taking your capsules at the same time each day will help you remember when to take them. Inhale the content of 4 capsules twice a day as follows:

- 4 capsules in the morning to be inhaled using the Podhaler device.
- 4 capsules in the evening to be inhaled using the Podhaler device.
- It is best to leave close to 12 hours between doses, but this must be at least 6 hours

If you are taking several different inhaled treatments and following other therapies for cystic fibrosis, you should take TOBI Podhaler after all of these are done. Please check the order of medications with your doctor.

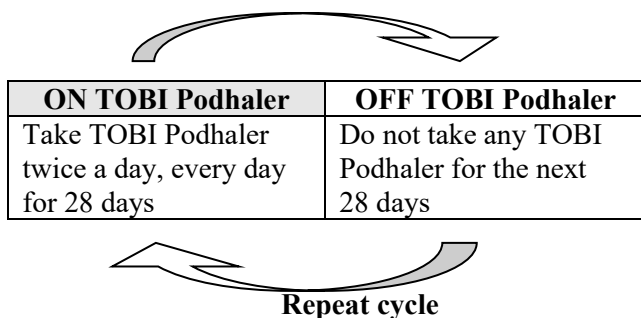
**How to take TOBI Podhaler**

- For inhalation use only.
- Do not swallow the capsules
- Only use the capsules with the inhaler provided in this pack. The capsules should remain in the capsule card until you need to use them.
- When you start a new weekly pack of capsules, use the new inhaler that is supplied in the pack. Each inhaler is only used for 7 days.
- Please read the instructions at the end of this leaflet for more information about how to use the inhaler.

**How long to take TOBI Podhaler**

After you have taken TOBI Podhaler for 28 days, you then have a 28-day break, during which you do not inhale any TOBI Podhaler. You then start another course.

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, 28-day off cycle.



Continue taking TOBI Podhaler as your doctor tells you.

If you have questions about how long to take TOBI Podhaler for, talk to your doctor or your pharmacist.

**If you take more TOBI Podhaler than you should**

If you inhale too much TOBI Podhaler, tell your doctor as soon as possible. If TOBI Podhaler is swallowed, don't worry but tell your doctor as soon as possible.

**If you forget to take TOBI Podhaler**

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 forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

People with cystic fibrosis have many symptoms of the disease. These may still happen while taking TOBI Podhaler, but should not be any more frequent or seem worse than before.

If your underlying lung disease seems worse while taking TOBI Podhaler, **tell your doctor straight away.**

**Some side effects can be serious**

- Unusual difficulty in breathing with wheezing or coughing and chest tightness (common).  
If you experience any of these, **stop taking TOBI Podhaler and tell your doctor straight away.**

- Coughing up blood (very common)
- Decreasing hearing (ringing in the ears is a potential warning sign of hearing loss), noises (such as hissing) in the ears (common).
- Low urine volume, vomiting, confusion and swelling in the legs, ankles or feet, as these may be signs of sudden decrease in kidney function (not known)

If you experience any of these, **tell your doctor straight away.**

**Other side effects may include:**

Very common (may affect more than 1 in 10 people)

- Shortness of breath
- Cough, productive cough, voice alteration (hoarseness)
- Sore throat
- Fever

Common (may affect up to 1 in 10 people)

- Wheezing, rales (crackles)

- Chest discomfort, chest pain from muscles or skeletal origins
- Blocked nose
- Nosebleed
- Vomiting, nausea
- Diarrhoea
- Rash
- Disturbed sense of taste.
- Loss of voice

Not known (frequency cannot be estimated from the available data)

- Generally feeling unwell
- Discoloration of the substance you cough up (sputum)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

United Kingdom

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

Or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store TOBI Podhaler**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the box or capsule card.
- Store in the original packaging in order to protect from moisture.

**Once removed from the capsule card (blister), a capsule should be used immediately.**

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What TOBI Podhaler contains**

- The active substance is tobramycin. One capsule contains 28 mg tobramycin.
- The other ingredients are DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), calcium chloride, sulfuric acid (for pH adjustment).

### **What TOBI Podhaler looks like and contents of the pack**

TOBI Podhaler inhalation powder, hard capsules consist of a white to almost white powder for inhalation filled into clear colourless hard capsules with “MYL TPH” imprinted in blue ink on one part of the capsule and the Mylan logo imprinted in blue on the other part of the capsule.

TOBI Podhaler is supplied in monthly packs containing 4 weekly cartons and a reserve Podhaler device in its storage case.

Each weekly carton contains 7 blisters (capsule cards) of 8 capsules each, and a Podhaler device in its storage case.

The following pack sizes are available:

56 inhalation powder, hard capsules and 1 inhaler (weekly pack)

224 (4 x 56) inhalation powder, hard capsules and 5 inhalers (monthly multipack)

448 (8 x 56) inhalation powder, hard capsules and 10 inhalers (2 x monthly multipack wrapped in foil)

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Viartis Products Limited,

Station Close,

Potters Bar,

EN6 1TL,

United Kingdom.

**Manufacturers**

McDermott Laboratories Ltd T/A Mylan Dublin Respiratory

Unit 25, Baldoyle Industrial Estate

Grange Road, Baldoyle

Dublin 13, D13 N5X2

Ireland

Mylan Germany GmbH

Zweigniederlassung Bad Homburg v. d. Hoehe

Benzstrasse 1

61352 Bad Homburg v. d. Hoehe

Germany

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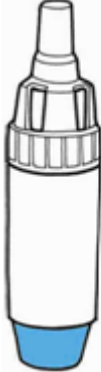
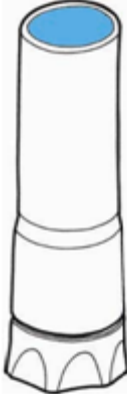
## INSTRUCTIONS FOR USE OF THE PODHALER DEVICE

Please read the following instructions carefully to learn how to use and care for your Podhaler device.

### Inside your TOBI Podhaler weekly pack



Each weekly carton of TOBI Podhaler contains:


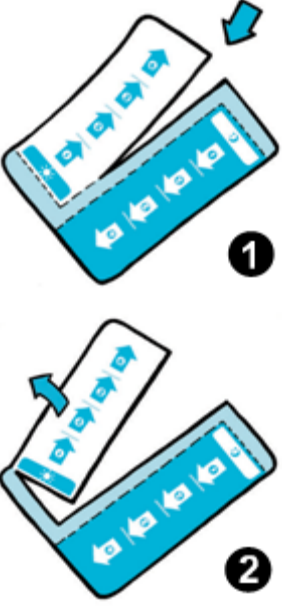


- 1 inhaler (the Podhaler device) and its storage case.
- 7 capsule cards (one card for each day of the week).
- Each capsule card contains 8 capsules (corresponding to a daily dose: content of 4 capsules to be inhaled in the morning and content of 4 capsules to be inhaled in the evening).




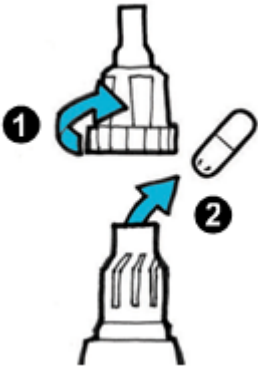

		
<b>Capsule card</b>	<b>Inhaler</b>	<b>Storage case</b>



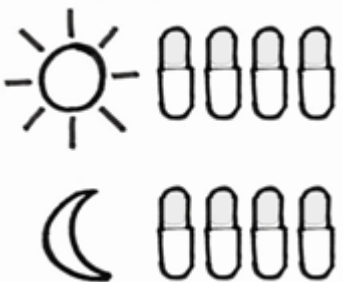

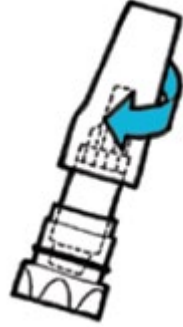
### How to inhale your medicine with the Podhaler device

- **Only use Podhaler device contained in this pack.** Do not use TOBI Podhaler capsules with any other device, and do not use the Podhaler device to take any other medicine.
- When you start a new weekly pack of capsules, use the new Podhaler device that is supplied in the pack. Each Podhaler device is only used for 7 days. Ask your pharmacist how to dispose of medicines and inhalers no longer required.
- **Do not swallow the capsules.** The powder in the capsules is for you to inhale.
- Always keep the capsules in the capsule card until when you need to use them. Do not take the capsules out of the card in advance.
- Store the Podhaler device in its tightly closed case when not in use.

	<p>1. Wash and <b>fully dry your hands</b>.</p>
	<p>2.</p> <ul style="list-style-type: none"> <li>• Just before use, remove the inhaler from its case by holding the base and twisting off the top of the case in an anti-clockwise direction.</li> <li>• Set the top of the case aside.</li> <li>• Look at the inhaler to make sure it is not damaged or dirty.</li> <li>• Stand the inhaler upright in the base of the case.</li> </ul>

	<p>3.</p> <ul style="list-style-type: none"> <li>• Hold the body of the inhaler and unscrew the mouthpiece in an anti-clockwise direction.</li> <li>• Set the mouthpiece aside on a clean, dry surface.</li> </ul>
	<p>4.</p> <p>Tear along the perforations of the capsule card lengthwise then widthwise, as indicated in pictures (1) and (2).</p>
	<p>5.</p> <ul style="list-style-type: none"> <li>• Peel back the foil from the capsule card to reveal one capsule only.</li> <li>• Remove the capsule from the card.</li> </ul>
	<p>6.</p> <ul style="list-style-type: none"> <li>• Put the capsule into the inhaler chamber straightaway (1).</li> <li>• Replace the mouthpiece.</li> <li>• Screw the mouthpiece on firmly until it stops. Do not overtighten (2).</li> </ul>

	<p>7.</p> <ul style="list-style-type: none"> <li>• Hold the inhaler <b>with the mouthpiece pointing down</b></li> <li>• Pierce the capsule by pressing firmly the blue button with your thumb as far as it will go, then release the button.</li> <li>• You are now ready to inhale the capsule in 2 separate breaths (Steps 8 and 9).</li> </ul>
	<p>8. <b>Inhale the capsule – 1<sup>st</sup> breath:</b>        Before putting the mouthpiece in your mouth, breathe out fully, away from the inhaler.        Place your mouth over the mouthpiece – to make a tight seal.        Inhale the powder deeply with a single breath.        Remove the inhaler from your mouth, and hold your breath for about 5 seconds.        Then breathe out normally, away from the inhaler.</p>
	<p>9. <b>Inhale the capsule – 2<sup>nd</sup> breath:</b></p> <ul style="list-style-type: none"> <li>• Take a few normal breaths away from the inhaler.</li> <li>• When you are ready, take your 2<sup>nd</sup> breath by repeating Step 8, using the same capsule.</li> </ul>
	<p>10. Unscrew mouthpiece (1) and remove the capsule from the chamber (2).</p>
	<p>11. <b>Look at the used capsule. It should appear pierced and empty.</b> If it is empty, discard the capsule.</p>

	<p>If the capsule is pierced but still contains some powder:</p> <ul style="list-style-type: none"> <li>• Put the capsule back into the inhaler chamber (step 6).</li> <li>• Put the pierced side of the capsule in first.</li> <li>• Replace the mouthpiece and repeat steps 8,9 and 10.</li> </ul>
	<p>If the capsule does not look pierced:</p> <ul style="list-style-type: none"> <li>• Put the capsule back into the inhaler chamber (step 6)</li> <li>• Replace the mouthpiece and repeat Steps 7, 8 and 9.</li> <li>• After this if the capsule is still full and appears not to be pierced, replace the inhaler with the reserve inhaler and repeat Steps 2, 3, 6, 7, 8, 9 and 10.</li> </ul>
	<p>12. Take the other 3 capsules in the same way.</p> <ul style="list-style-type: none"> <li>• So for each remaining capsule, repeat steps 5,6, 7, 8, 9, 10 and 11.</li> <li>• Discard all the empty capsules.</li> </ul>
	<p>13. • 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> <ul style="list-style-type: none"> <li>• <b>Do not wash the inhaler with water.</b></li> </ul>
	<p>14. • Place inhaler back in storage case</p> <ul style="list-style-type: none"> <li>• Twist the top of the case in a clockwise direction until it is closed tightly.</li> </ul>

**REMEMBER:**

- For inhalation use only.
- **Do not swallow TOBI Podhaler capsules.**
- **Only use the inhaler contained in this pack.**
- Always keep the TOBI Podhaler capsules in the capsule card. Only remove a capsule just before you are going to use it. Do not store the capsules in the inhaler.
- Always keep the TOBI Podhaler capsules and device in a dry place.

- Never place a TOBI Podhaler capsule directly into the mouthpiece of the device.
- Always hold the device with the mouthpiece pointing down when piercing the capsule.
- Do not press the piercing button more than once at a time.
- Never blow into the mouthpiece of the device.
- Never wash the Podhaler device with water. Keep it dry and store it in its case.

**Additional information**

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 or if the device is not held with the mouthpiece pointing down during step 7.