



# TOBI<sup>®</sup> Podhaler<sup>®</sup>

Tobramycin Inhalation Powder  
28 mg per capsule

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## How To Use Guide



### INDICATION

TOBI<sup>®</sup> PODHALER<sup>®</sup> (Tobramycin Inhalation Powder) 28 mg per capsule is a prescription inhaled medication for cystic fibrosis patients whose lungs contain bacteria called *Pseudomonas aeruginosa*.

It is not known if TOBI PODHALER is safe and effective in patients under 6 years of age, in those with lung function outside of a certain range, or in those whose lungs contain bacteria called *Burkholderia cepacia*.

### IMPORTANT SAFETY INFORMATION

**Do not swallow TOBI PODHALER capsules. TOBI PODHALER capsules are used only with the Podhaler device and inhaled through your mouth (oral inhalation). Never place a capsule in the mouthpiece of the Podhaler device.**

You should not use TOBI PODHALER if you are allergic to it or to any other aminoglycoside antibacterial medicines.

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[Click here for full Prescribing Information and Patient Information](#)



### Important Information:

- Your healthcare provider should show you or a caregiver how to use TOBI Podhaler the right way before you use it for the first time. Ask your healthcare provider if you have any questions or are not sure how to use TOBI Podhaler the right way.
- The recommended dose of TOBI Podhaler is 4 capsules inhaled twice daily. Each blister card has 8 TOBI Podhaler capsules - 4 capsules for inhalation in the morning and 4 capsules for inhalation in the evening.
- You must inhale all of the powdered medicine from all 4 TOBI Podhaler capsules to get the full dose. If all of the powdered TOBI Podhaler medicine is not inhaled, you will not get the full dose.
  - After you have inhaled 2 times from a capsule, remove the capsule from the capsule chamber and hold the used capsule up to the light and look through it. It should be empty with only a fine coating of powder left on the inside surface of the capsule.
    - If the capsule is empty, throw it away and continue following the Instructions for Use.
    - If the capsule is not empty, review below “What to do with a capsule that has not been emptied” for instructions.
- You or a caregiver should tell your healthcare provider as soon as possible if you think you or your child has not received the full TOBI Podhaler dose. Your healthcare provider should show you how to use TOBI Podhaler the right way.

### IMPORTANT SAFETY INFORMATION (Continued)

**Tell your doctor before starting treatment** all of your medical conditions, including if you have or have had hearing problems, dizziness, kidney problems, muscle weakness, breathing problems such as wheezing, coughing or chest tightness, if you had an organ transplant, are pregnant or nursing or plan to become pregnant or nurse.

TOBI PODHALER contains a medicine that can harm your unborn baby. It is not known if it passes into breast milk. Check your baby for watery stools, bloody stools, thrush or diaper rash if you breast feed.

**Tell your doctor about all the medicines you take** including over-the-counter medicines, vitamins, and herbal supplements. If you are using TOBI PODHALER, discuss if you should take other medicines that may harm your nervous system, kidneys, or hearing; "water pills" (diuretics) such as EDECRIN<sup>®</sup> (ethacrynic acid), LASIX<sup>®</sup> (furosemide), or intravenous mannitol; urea.

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Follow the instructions below for using your TOBI Podhaler. You will breathe in (inhale) the medicine in the TOBI Podhaler capsules using the Podhaler device. If you have any questions, ask your healthcare provider or pharmacist.

TOBI Podhaler is available as a 28-day, 7-day, and 1-day supply package.

Each TOBI Podhaler package contains:

- 4 weekly packs (28-day supply), each containing:
  - 56 capsules (7 blister cards of 8 capsules). Each blister card contains 8 TOBI Podhaler capsules (4 capsules for inhalation in the morning and 4 capsules for inhalation in the evening).
  - 1 Podhaler device and its storage case.
- 1 reserve Podhaler device (to be used if needed) and its storage case.

Or:

- A 7-day pack (7-day supply) containing:
  - 56 capsules (7 blister cards of 8 capsules). Each blister card contains 8 TOBI Podhaler capsules (4 capsules for inhalation in the morning and 4 capsules for inhalation in the evening).
  - 1 Podhaler device and its storage case.

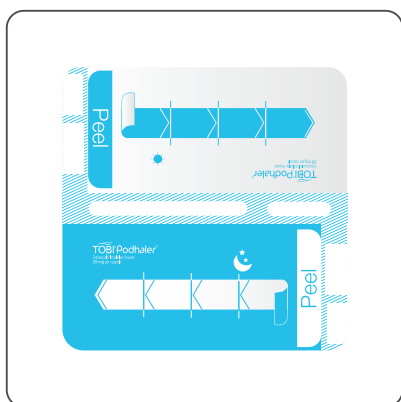
Or:

- A 1-day pack (1-day supply) containing:
  - 8 capsules (1 blister card of 8 capsules). Each blister card contains 8 TOBI Podhaler capsules (4 capsules for inhalation in the morning and 4 capsules for inhalation in the evening).
  - 1 Podhaler device and its storage case.

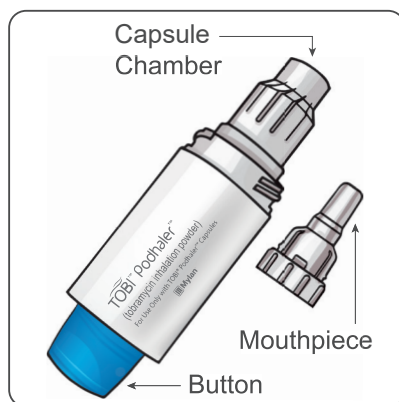
### **IMPORTANT SAFETY INFORMATION (Continued)**

TOBI PODHALER can cause **serious side effects**, including:

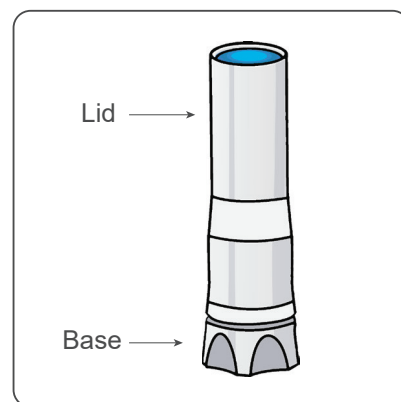
**Severe breathing problems (bronchospasm)**. Tell your doctor right away if you get shortness of breath with wheezing or coughing and chest tightness while using TOBI PODHALER.



**Blister Card**



**Podhaler device**



**Storage case**

**Note:**

- **Do not** swallow TOBI Podhaler capsules. The powder in the capsule is for you to inhale using the Podhaler device.
- Only use the 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 (7-day) pack of capsules, use the new Podhaler device that is supplied in the pack and discard the used device and its case. Each Podhaler device is only used for one week (7 days).
- Always keep the TOBI Podhaler capsules in the blister card. Only remove 1 capsule at a time just before you are going to use it.
- Doses should be inhaled as close to 12 hours apart as possible and not less than 6 hours apart.

**IMPORTANT SAFETY INFORMATION (Continued)**

**Hearing loss or ringing in the ears (ototoxicity).** Tell your doctor right away if you have hearing loss, noises in your ears such as ringing or hissing, vertigo, difficulty with balance, dizziness, or your mother has had hearing problems after taking an aminoglycoside. Tell your doctor if you have been told you have certain gene variants (a change in the gene) related to hearing abnormalities inherited from your mother.

**Worsening kidney problems (nephrotoxicity).** TOBI PODHALER is in a class of medicines that may cause worsening kidney problems, especially in people with known or suspected kidney problems. Your healthcare provider may do a blood test to check how your kidneys are working while you are using TOBI PODHALER.

**Note : (continued)**

- Once in a while, very small pieces of the capsules can get into your mouth and you may be able to feel these pieces on your tongue. These small pieces will not hurt you if you swallow or inhale them.
- The reserve Podhaler device provided in the 28-day supply package may be used if the Podhaler device:
  - is wet, dirty, or broken
  - has been dropped
  - does not seem to be piercing the capsule properly (See Step 17)



**Getting ready:**

- Wash and dry your hands.

**IMPORTANT SAFETY INFORMATION (Continued)**

**Worsening muscle weakness.** TOBI PODHALER is in a class of medicines that can cause worsening muscle weakness in people who already have problems with muscle weakness (myasthenia gravis or Parkinson's disease).

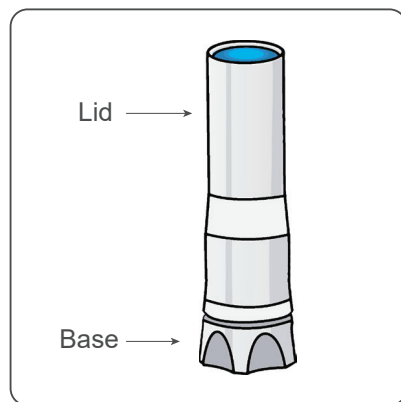
**TOBI PODHALER is in a class of medicines which may cause harm to an unborn baby.**

**The most common side effects of TOBI PODHALER include** cough, worsening of lung problems or cystic fibrosis, productive cough, shortness of breath, fever, sore throat, changes in your voice (hoarseness), coughing up blood, and headache.

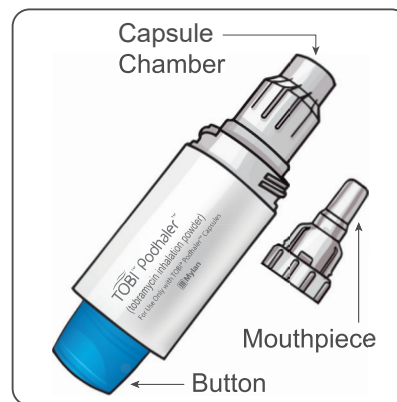
Let your doctor know if your symptoms worsen or if you have a side effect that bothers you enough to stop treatment or that does not go away.

## Preparing your TOBI Podhaler dose

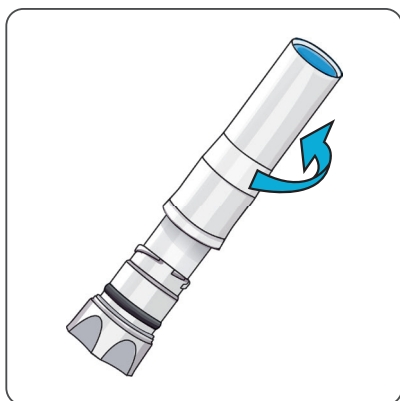
Your Podhaler device comes in a storage case with a lid. The device itself has a removable mouthpiece, a capsule chamber and a button at its base.



**Storage case**



**Podhaler device**

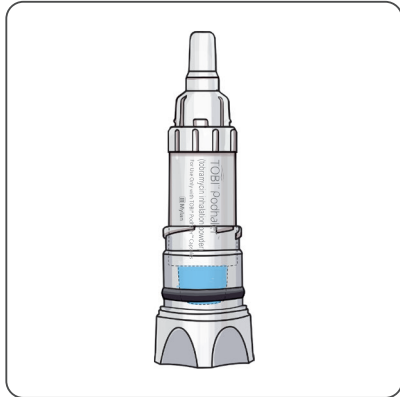


**Step 1:** Just before use, hold the base of the storage case and unscrew the lid in a counter-clockwise direction. Set the lid aside.

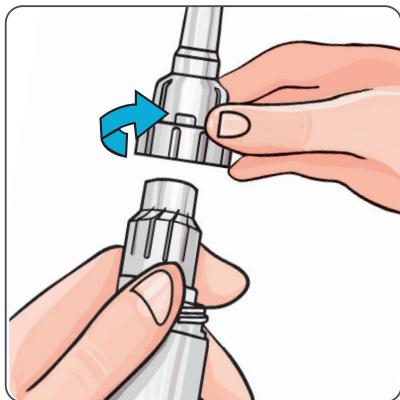
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**Step 2:** Leave the Podhaler device in the base of the case while you prepare your dose.



**Step 3:** Hold the body of the Podhaler device and unscrew the mouthpiece in a counter-clockwise direction. Set the mouthpiece aside on a clean, dry surface.

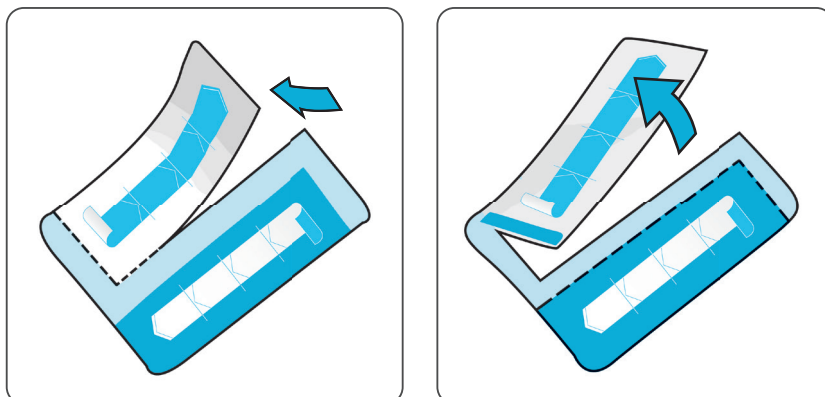
**Note:** Each blister card contains 8 TOBI Podhaler capsules - 4 capsules for inhalation in the morning and 4 capsules for inhalation in the evening.

### **IMPORTANT SAFETY INFORMATION**

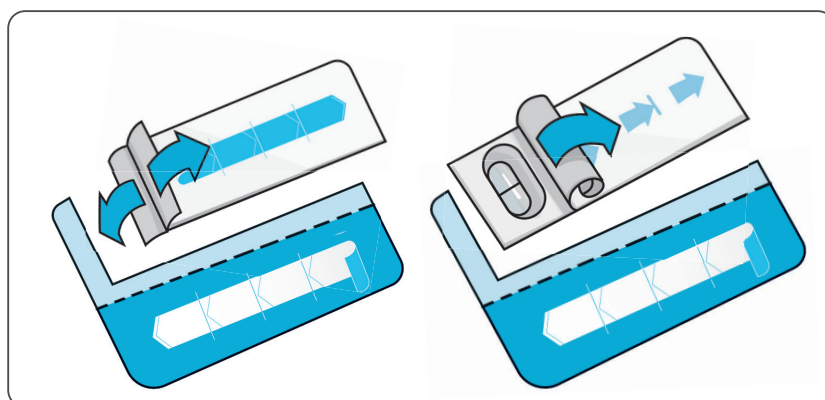
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**Step 4:** Take 1 blister card and tear the pre-cut lines along the length then tear at the pre-cut lines along the width.



**Step 5:** Peel (by rolling back) the foil that covers 1 TOBI Podhaler capsule on the blister card. Always hold the foil close to where you are peeling.

#### **IMPORTANT SAFETY INFORMATION (Continued)**

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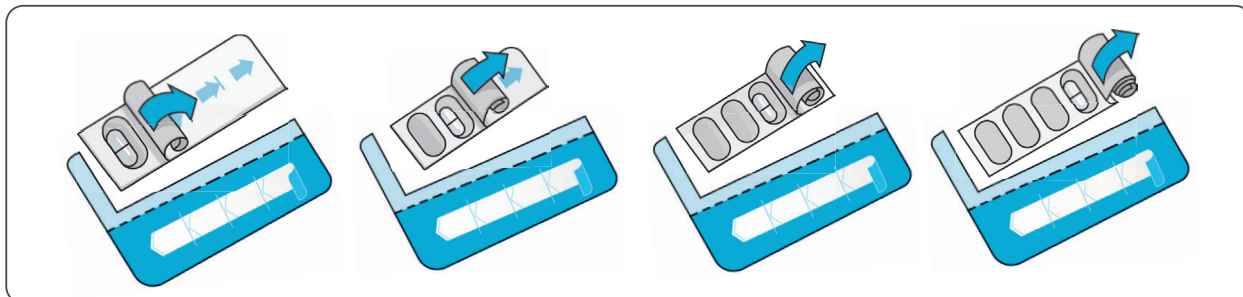
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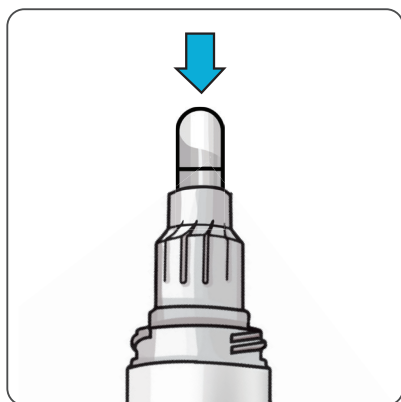
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**Step 6:** Take out 1 TOBI Podhaler capsule from the blister card.

**Note:** Only peel back the foil from one capsule at a time and remove the capsule just before you are going to use it in the device because the blister protects the capsule from moisture.



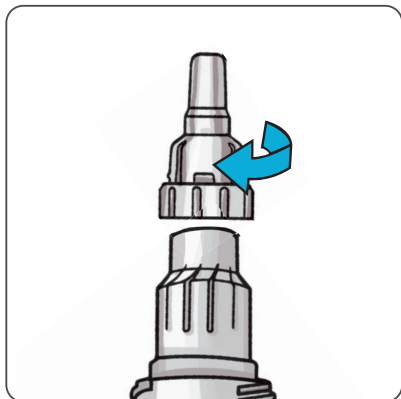
**Step 7:** Place the TOBI Podhaler capsule in the capsule chamber at the top of the Podhaler device right away. **Do not** put the capsule directly into the top of the mouthpiece.

#### **IMPORTANT SAFETY INFORMATION (Continued)**

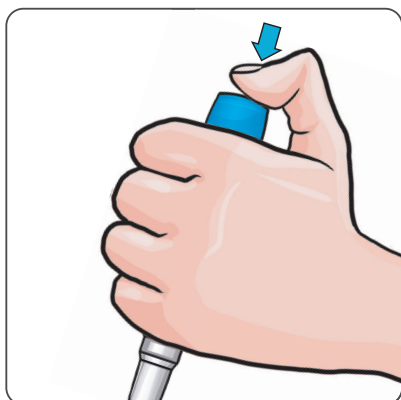
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**Worsening muscle weakness.** TOBI PODHALER is in a class of medicines that can cause worsening muscle weakness in people who already have problems with muscle weakness (myasthenia gravis or Parkinson's disease).

**TOBI PODHALER is in a class of medicines which may cause harm to an unborn baby.**



**Step 8:** Put the mouthpiece back on your Podhaler device and screw the mouthpiece in a clockwise direction until it is tight. **Do not** overtighten.



**Step 9:** Remove the Podhaler device from the base of the case. Hold the Podhaler device with the mouthpiece pointing down. Put your thumb on the blue button and press the blue button all the way down. Let go of the blue button. **Do not** press the blue button more than 1 time. The chances of the capsule breaking into pieces will be increased if the capsule is accidentally pierced more than once.

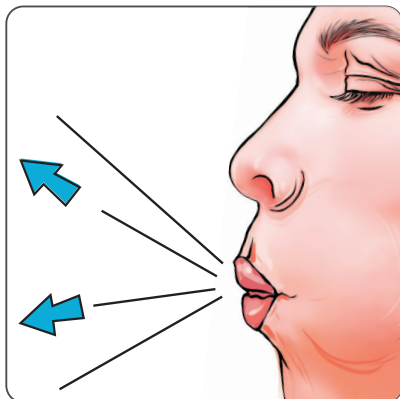
### **IMPORTANT SAFETY INFORMATION (Continued)**

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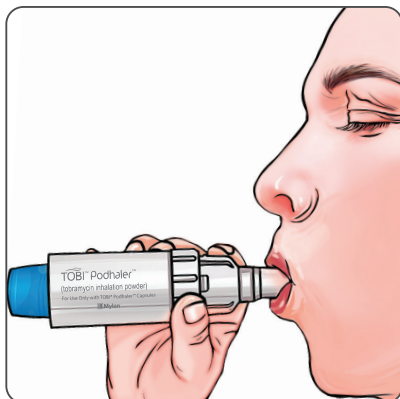
Let your doctor know if your symptoms worsen or if you have a side effect that bothers you enough to stop treatment or that does not go away.

## Taking your TOBI Podhaler dose

(you will need to repeat steps 10 to 14 for each capsule so you inhale each capsule 2 times in order to empty it):



**Step 10:** Breathe out (exhale) all the way.  
**Do not** blow or exhale into the mouthpiece.

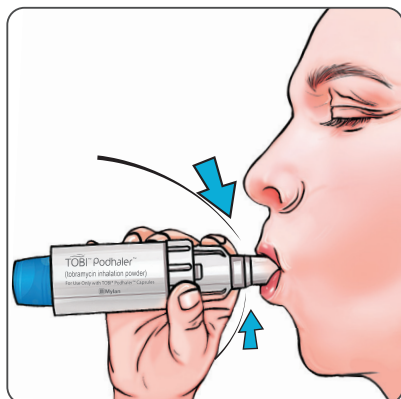


**Step 11:** Place your mouth over the mouthpiece and close your lips tightly around it.

### INDICATION

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**Step 12:** Inhale deeply with a single breath.

**Step 13:** Remove the Podhaler device from your mouth, and **hold your breath** for about 5 seconds.

**Step 14:** Exhale and take a few normal breaths away from the Podhaler device. **Do not** blow or exhale into the mouthpiece.

**Step 15:** Repeat steps 10 through 14 **using the same capsule**.

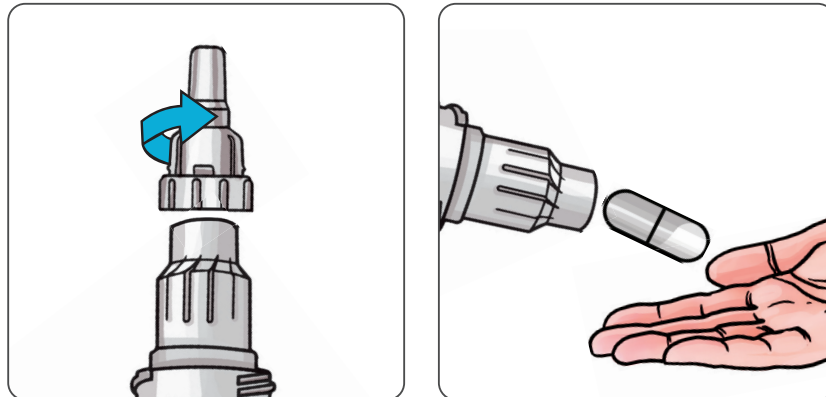
- You must **inhale 2 times from each capsule** in order to empty it.

### IMPORTANT SAFETY INFORMATION

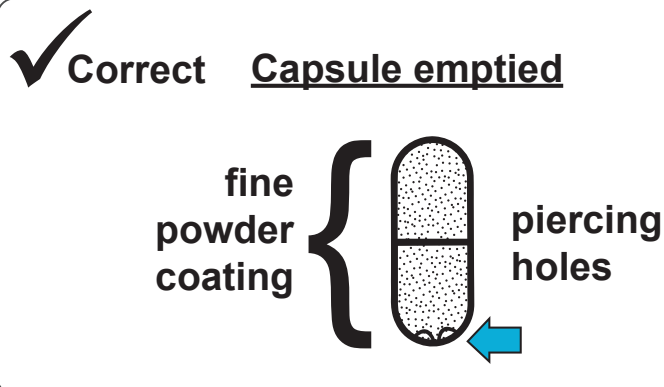
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**Tell your doctor before starting treatment** all of your medical conditions, including if you have or have had hearing problems, dizziness, kidney problems, muscle weakness, breathing problems such as wheezing, coughing or chest tightness, if you had an organ transplant, are pregnant or nursing or plan to become pregnant or nurse.



**Step 16:** Unscrew the mouthpiece and remove the TOBI Podhaler capsule from the capsule chamber.



**Step 17:** Hold the used capsule up to the light and look through it. It should be empty with only a fine coating of powder remaining on the inside surface of the capsule. If the capsule is empty, throw it away and go to Step 18.

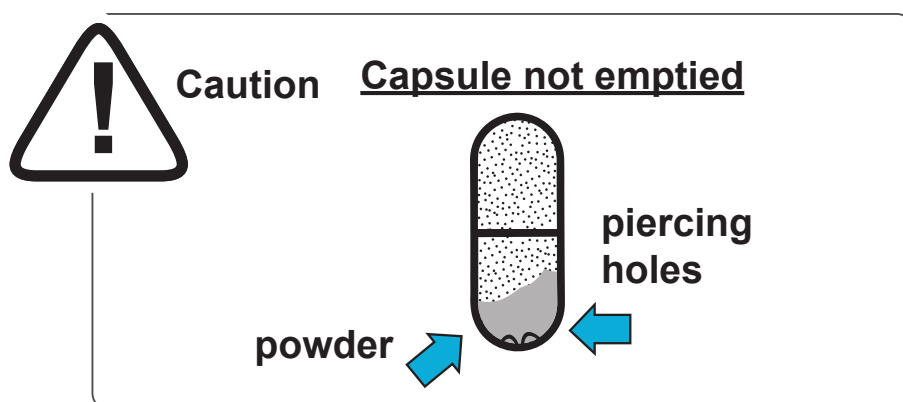
If the capsule **is not** empty, see “What to do with a capsule that has not been emptied” below for instructions.

### **IMPORTANT SAFETY INFORMATION (Continued)**

TOBI PODHALER contains a medicine that can harm your unborn baby. It is not known if it passes into breast milk. Check your baby for watery stools, bloody stools, thrush or diaper rash if you breast feed.

### What to do with a capsule that has not been emptied:

- If the capsule is pierced but still contains more than just a fine coating of powder you must inhale from it again twice:
  - Put the capsule back into the Podhaler device capsule chamber with the pierced side of the capsule pointing down.
  - Screw the mouthpiece back on until it is tight.
  - Repeat Steps 10 to 17.

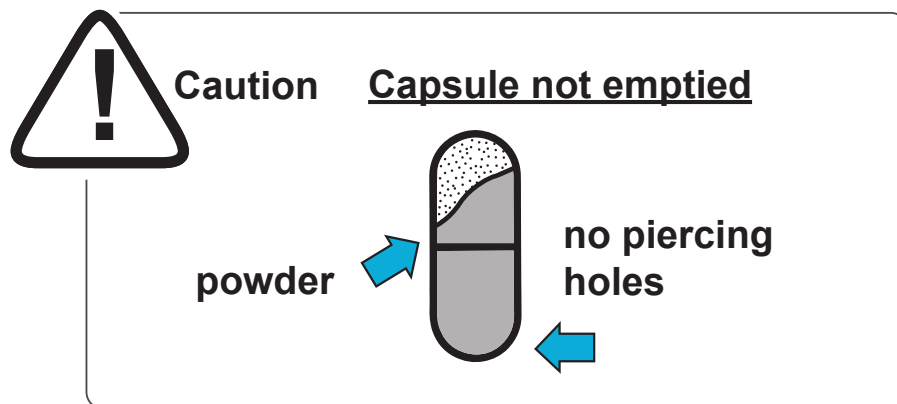


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- If the capsule is not pierced you must pierce it again and inhale from it twice:
  - Put the capsule back into the Podhaler device capsule chamber.
  - Screw the mouthpiece back on until it is tight.
  - Repeat Steps 9 to 17 making sure to press the blue button all the way down.



**Note:** If you have tried to pierce the capsule 2 times and it is still not pierced, use the reserve Podhaler device provided in the TOBI Podhaler package instead (only available in the 28-day supply package). If you need a new device, ask your physician.

- Prepare the reserve Podhaler device by following Steps 1 to 3.
- Then, using the same capsule, repeat Steps 7 to 17.

**1 dose =** 

**Step 18:** Repeat Steps 5 to 17 for 3 more times until your whole dose (4 capsules) has been taken.

#### **IMPORTANT SAFETY INFORMATION (Continued)**

TOBI PODHALER can cause **serious side effects**, including:

**Severe breathing problems (bronchospasm).** Tell your doctor right away if you get shortness of breath with wheezing or coughing and chest tightness while using TOBI PODHALER.

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## After your TOBI Podhaler dose:

**Step 19:** Throw away all the empty TOBI Podhaler capsules. **Do not** store the TOBI Podhaler capsules in the Podhaler device.

**Step 20:** Put the mouthpiece back on to your Podhaler device and twist the mouthpiece in a clockwise direction until it is tight. **Do not** overtighten.



**Step 21:** Wipe the mouthpiece with a clean, **dry cloth**.

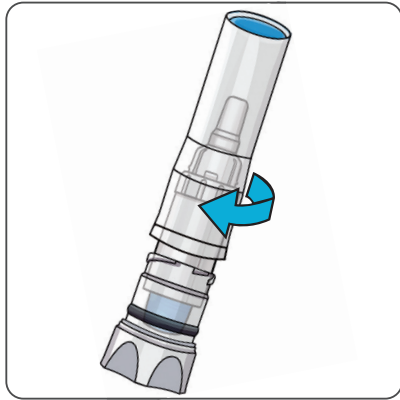
**Do not** wash the Podhaler device with water. Your Podhaler device needs to stay dry at all times to work the right way.

**Step 22:** Place your Podhaler device back in the storage case base.

### **IMPORTANT SAFETY INFORMATION (Continued)**

**Hearing loss or ringing in the ears (ototoxicity).** Tell your doctor right away if you have hearing loss, noises in your ears such as ringing or hissing, vertigo, difficulty with balance, dizziness, or your mother has had hearing problems after taking an aminoglycoside. Tell your doctor if you have been told you have certain gene variants (a change in the gene) related to hearing abnormalities inherited from your mother.

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**Step 23:** Place the lid back on the storage case base and screw the cover in a clockwise direction until it is tight.

### How should I store TOBI Podhaler?

- Store your Podhaler device and blister-packaged capsules at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep the TOBI Podhaler capsules and Podhaler device in a dry place.**
- Store the Podhaler device tightly closed in its case when you are not using it.
- Keep TOBI Podhaler capsules, Podhaler device, and all medicines out of the reach of children.

### IMPORTANT SAFETY INFORMATION (Continued)

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You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

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