

Patient Information

TOBI (TOH-bee) Podhaler (POD-hay-ler)

(tobramycin inhalation powder)

For Oral Inhalation

Important 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.

Read this Patient Information before you start using TOBI Podhaler and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is TOBI Podhaler?

TOBI Podhaler is a prescription medicine used to treat people with cystic fibrosis who have a bacterial infection called *Pseudomonas aeruginosa*. TOBI Podhaler contains an antibacterial medicine called tobramycin (an aminoglycoside).

It is not known if TOBI Podhaler is safe and effective:

- in children under 6 years of age
- in people who have an FEV₁ less than 25% predicted
- in people who are colonized with a bacterium called *Burkholderia cepacia*
- when used for more than 3 cycles

Who should not use TOBI Podhaler?

Do not use TOBI Podhaler if you are allergic to tobramycin, any of the ingredients in TOBI Podhaler, or to any other aminoglycoside antibacterial.

What should I tell my healthcare provider before using TOBI Podhaler?

Before you use TOBI Podhaler, tell your healthcare provider if you:

- have or have had hearing problems (including noises in your ears such as ringing or hissing)
- have dizziness
- have or have had kidney problems
- have or have had problems with muscle weakness such as myasthenia gravis or Parkinson's disease
- have or have had breathing problems such as wheezing, coughing, or chest tightness
- have had an organ transplant
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed. It is not known if TOBI Podhaler passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using TOBI Podhaler with certain other medicines can cause serious side effects.

If you are using TOBI Podhaler, you should discuss with your healthcare provider if you should take:

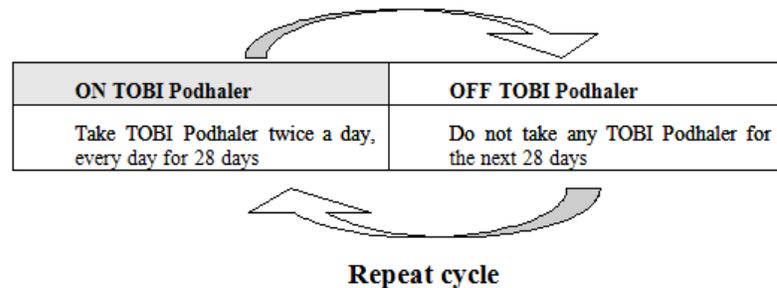
- other medicines that may harm your nervous system, kidneys, or hearing
- “water pills” (diuretics) such as Edecrin (ethacrynic acid), Lasix (furosemide), or intravenous mannitol
- urea

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I use TOBI Podhaler?

- See the step-by-step Instructions for Use at the end of this Patient Information leaflet about the right way to use TOBI Podhaler. Do not use TOBI Podhaler unless your healthcare provider has taught you how to use it the right way. Ask your healthcare provider or pharmacist if you are not sure.
- Always use TOBI Podhaler exactly as your healthcare provider tells you to use it. Ask your healthcare provider or pharmacist if you are not sure.
- The usual dose for adults and children over 6 years of age is:
 - The content of 4 TOBI Podhaler capsules inhaled by mouth in the morning using your Podhaler device and the content of 4 TOBI Podhaler capsules inhaled by mouth in the evening using your Podhaler device.
 - Check to see that each capsule is empty after inhaling. If powder remains in the capsule, repeat inhalation until the capsule is empty.
- Each dose of 4 TOBI Podhaler capsules should be taken as close to 12 hours as possible.
- You should not take your dose of 4 TOBI Podhaler capsules less than 6 hours apart.
- 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 double the dose to make up for the missed dose.
- After using TOBI Podhaler for 28 days, you should stop using it and wait 28 days. After you have stopped using TOBI Podhaler for 28 days, you should start using TOBI Podhaler again for 28 days. Complete the full 28-day course even if you are feeling better. It is important that you keep to the 28-day on, 28-day off cycle (See Figure A).



(Figure A)

- If you have been prescribed a 7-day pack of TOBI Podhaler either immediately before or during a 28-day treatment with TOBI Podhaler, then you must count each day of use toward the 28-day on-treatment part of the cycle. You should only take a total of 28 consecutive days of treatment during a cycle.
- If you have been prescribed a 1-day pack of TOBI Podhaler either immediately before or during a 28-day treatment with TOBI Podhaler, then you must count each day of use toward the 28-day on-treatment part of the cycle. You should only take a total of 28 consecutive days of treatment during a cycle.
- If you are taking several different medicines inhaled through your mouth, your healthcare provider will tell you how to take your medicines the right way.
- If you are doing therapies for cystic fibrosis (chest physiotherapy), you should take TOBI Podhaler after your therapies are done.
- If you inhale too much TOBI Podhaler, tell your healthcare provider right away.
- If you accidentally swallow TOBI Podhaler capsules, tell your healthcare provider right away.
- Use a new Podhaler device every 7 days.
- Caregivers should help children who are 10 years of age and younger use TOBI Podhaler, and should keep watching them use their TOBI Podhaler until they are able to use it the right way without help.

What are the possible side effects of TOBI Podhaler?

TOBI Podhaler can cause serious side effects, including:

- hearing loss or ringing in the ears (ototoxicity). Tell your healthcare provider right away if you have hearing loss or you hear noises in your ears such as ringing or hissing. Tell your healthcare provider if you develop vertigo, difficulty with balance or dizziness.
- worsening kidney problems (nephrotoxicity). TOBI Podhaler is in a class of drugs which 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.
- worsening muscle weakness. TOBI Podhaler is in a class of drugs which can cause muscle weakness to get worse in people who already have problems with muscle weakness (myasthenia gravis or Parkinson's disease).
- severe breathing problems (bronchospasm). Tell your healthcare provider right away if you get any of these symptoms of bronchospasm with using TOBI Podhaler:
 - shortness of breath with wheezing
 - coughing and chest tightness
- TOBI Podhaler is in a class of drugs 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
- headache
- altered taste

Laboratory tests show reduced tobramycin activity against *Pseudomonas aeruginosa* bacteria in some patients with the use of TOBI Podhaler. The relationship between these lab results and how well TOBI Podhaler works is not clear. Let your healthcare provider know if your symptoms worsen.

Some patients may be unable to continue TOBI Podhaler and need to consider alternative therapies. Tell your healthcare provider about any side effect that bothers you enough to stop treatment or that does not go away.

These are not all of the possible side effects of TOBI Podhaler. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of TOBI Podhaler.

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use TOBI Podhaler for a condition for which it was not prescribed. Do not give TOBI Podhaler to other people, even if they have the same problem you have. It may harm them.

This leaflet summarizes the most important information about TOBI Podhaler. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about TOBI Podhaler that was written for healthcare professionals.

For more information, go to www.TOBIPodhaler.com or call 1-877-999-TOBI (8624).

What are the ingredients in TOBI Podhaler?

Active ingredient: tobramycin

Inactive ingredients: 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), calcium chloride, and sulfuric acid (for pH adjustment)

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 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 managed, it will continue to damage your lungs causing further problems to your breathing.

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Instructions for Use

TOBI Podhaler

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 (**See Figure S**).
 - 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.**

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 (See Figure A):

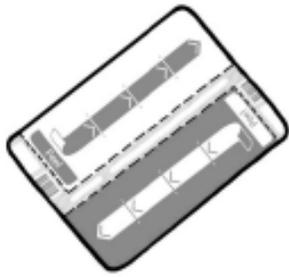
- 4 weekly packs (28-day supply), each containing:
 - 56 capsules (7 blister cards of 8 capsules). Each blister card contains 8 TOBI Podhaler capsules (4 capsules for inhalation in the morning and 4 capsules for inhalation in the evening).
 - 1 Podhaler device and its storage case
 - 1 reserve Podhaler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

Or:

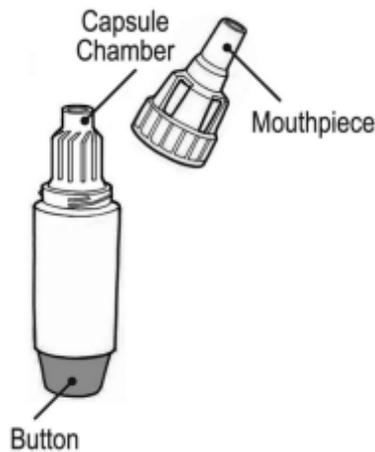
- A 7-day pack (7-day supply) containing:
 - 56 capsules (7 blister cards of 8 capsules). Each blister card contains 8 TOBI Podhaler capsules (4 capsules for inhalation in the morning and 4 capsules for inhalation in the evening).
 - 1 Podhaler device and its storage case

Or:

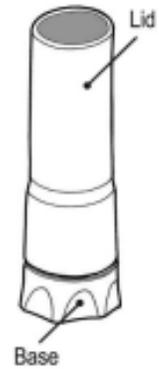
- A 1-day pack (1-day supply) containing:
 - 8 capsules (1 blister card of 8 capsules). Each blister card contains 8 TOBI Podhaler capsules (4 capsules for inhalation in the morning and 4 capsules for inhalation in the evening).
 - 1 Podhaler device and its storage case



Blister card



Podhaler device



Storage case

Figure A

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.
- 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** (See Figure B).



Figure B

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 (See Figure C).

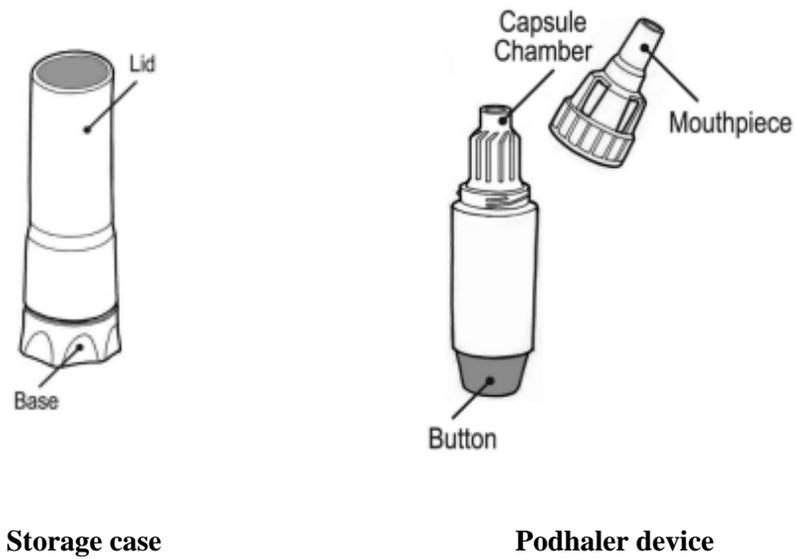


Figure C

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

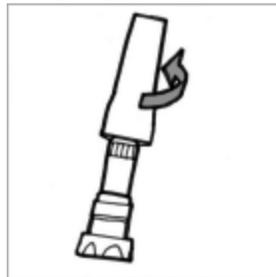


Figure D

Step 2: Leave the Podhaler device in the base of the case while you prepare your dose (See Figure E).



Figure E

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



Figure F

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

Step 4: Take 1 blister card and tear the pre-cut lines along the length (See Figure G) then tear at the pre-cut lines along the width (See Figure H).

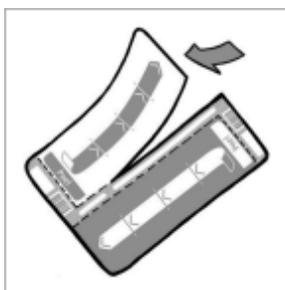


Figure G

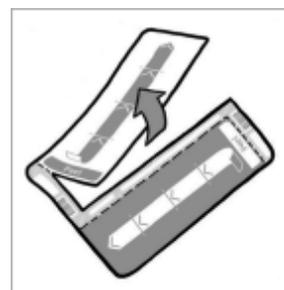


Figure H

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

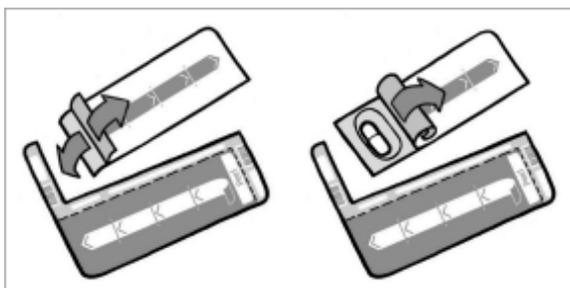


Figure I

Step 6: Take out 1 TOBI Podhaler capsule from the blister card (See Figure J). **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.

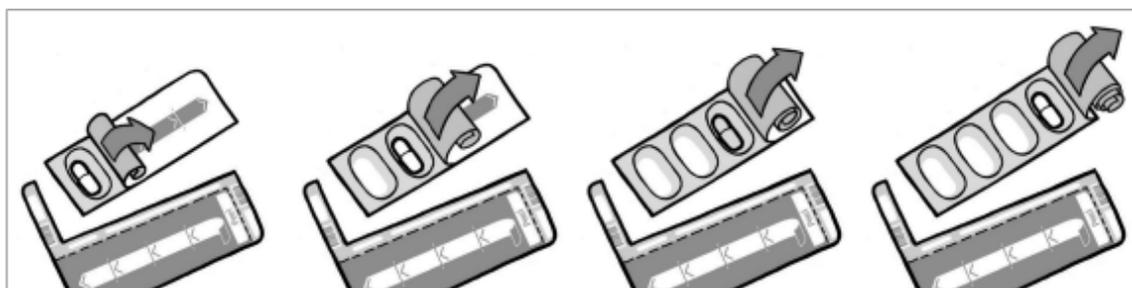


Figure J

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

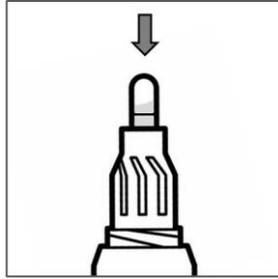


Figure K

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



Figure L

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 (See Figure M). 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.

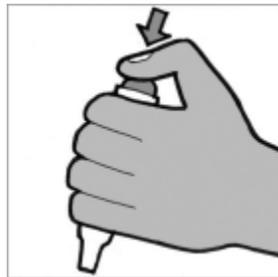


Figure M

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 (See Figure N). **Do not** blow or exhale into the mouthpiece.

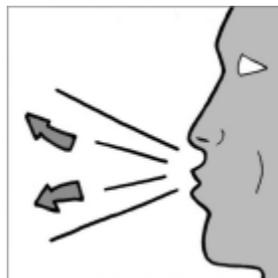


Figure N

Step 11: Place your mouth over the mouthpiece and close your lips tightly around it (See Figure O).



Figure O

Step 12: Inhale deeply with a single breath (See Figure P).



Figure P

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.

Step 16: Unscrew the mouthpiece and remove the TOBI Podhaler capsule from the capsule chamber (See Figures Q and R below).

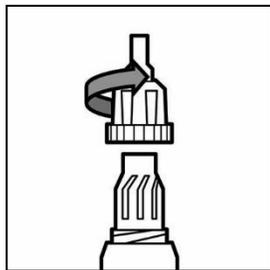


Figure Q

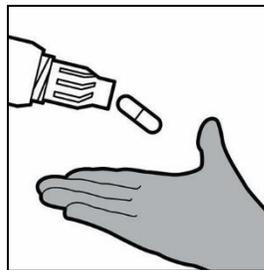


Figure R

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 (See Figure S). If the capsule is empty, throw it away and go to Step 18.

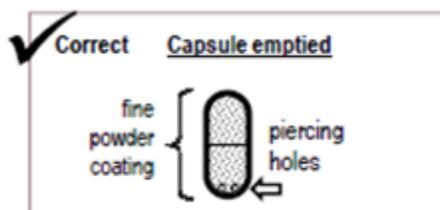


Figure S

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

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 (See **Figure T**) 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.

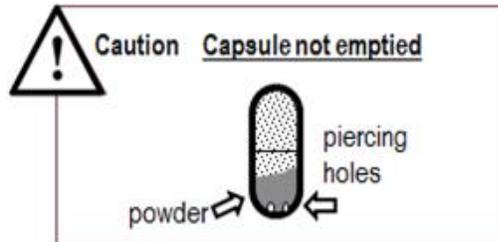


Figure T

- If the capsule is not pierced (See **Figure U**) 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.

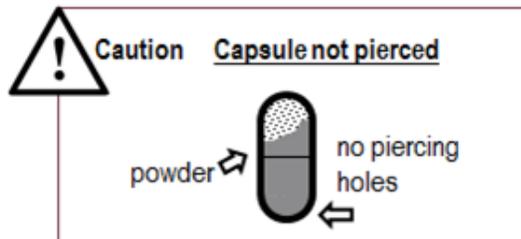


Figure U

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.

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

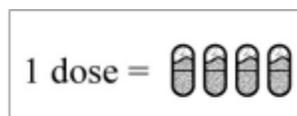


Figure V

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 (See Figure L). **Do not** overtighten.

Step 21: Wipe the mouthpiece with a clean, **dry cloth** (See Figure W).

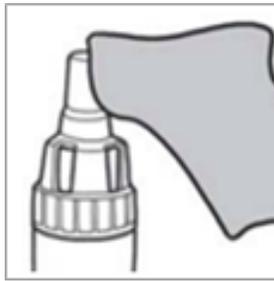


Figure W

- **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.

Step 23: Place the lid back on the storage case base and screw the cover in a clockwise direction until it is tight (See Figure X).

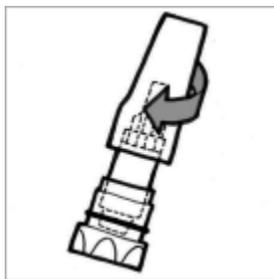


Figure X

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.

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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