

**PATIENT INFORMATION**  
**TOBI (TOH-bee)**  
**(tobramycin inhalation solution)**  
**for oral inhalation use**

**What is TOBI?**

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

It is not known if TOBI is safe and effective:

- in children under 6 years of age
- in people who have an FEV<sub>1</sub> less than 25% or greater than 75% predicted
- in people who are colonized with a bacterium called *Burkholderia cepacia*

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

**See the end of this Patient Information for a complete list of ingredients in TOBI.**

**Before you take TOBI, tell your healthcare provider about all of your medical conditions, including 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
- are pregnant or plan to become pregnant. TOBI is in a class of drugs that can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TOBI passes into your breast milk.
- are receiving aminoglycoside therapy by injection or through a vein (intravenous) while taking TOBI. Your blood levels of tobramycin will be checked.

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

**How should I take TOBI?**

- **See the step-by-step Instructions for Use** about the right way to take your TOBI.
- Take TOBI exactly as your healthcare provider tells you. **Do not** change your dose or stop taking TOBI unless your healthcare provider tells you to.
- The usual dose for adults and children over 6 years of age is:
  - 1 single-use ampule of TOBI inhaled 2 times each day using a hand-held PARI LC PLUS™ Reusable Nebulizer and a DeVilbiss® Pulmo-Aide® air compressor.
- Each dose of TOBI should be taken as close to 12 hours apart as possible.
- You should not take your dose less than 6 hours apart.
- TOBI is taken as a breathing treatment (inhalation) with a hand-held PARI LC PLUS Reusable Nebulizer with a DeVilbiss Pulmo-Aide compressor. **Do not** use any other nebulizer for your TOBI treatment.
- Do not mix or dilute TOBI with dornase alfa or other medicines in your nebulizer system.
- Each treatment should take about 15 minutes.
- TOBI should be inhaled while you are sitting or standing upright and breathing normally through the mouthpiece of the nebulizer. Nose clips may help you to breathe through your mouth.
- If you forget to take TOBI 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 for 28 days, you should stop using it and wait 28 days. After you have stopped using TOBI for 28 days, you should start using TOBI 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.

If you are taking several medicines or treatments to treat your cystic fibrosis, you should take your medicines or other treatments before inhaling TOBI or as directed by your healthcare provider. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter prescription medicines, vitamins, and herbal supplements.

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

If you are using TOBI, 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 ethacrynic acid, 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.

### **What are the possible side effects of TOBI?**

**TOBI may cause serious side effects, including:**

- severe breathing problems (bronchospasm). Tell your healthcare provider right away if you get any of these symptoms of bronchospasm with using TOBI:
  - shortness of breath with wheezing
  - coughing and chest tightness
- 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 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.
- worsening muscle weakness (neuromuscular disorder). TOBI 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).

The most common side effects of TOBI include:

- |                     |                           |                     |
|---------------------|---------------------------|---------------------|
| ○ increased cough   | ○ sore throat             | ○ increased sputum  |
| ○ coughing up blood | ○ decreased lung function | ○ trouble breathing |
| ○ voice changes     | ○ loss or change in taste | ○ rash              |

These are not all of the possible side effects of TOBI.

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**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use TOBI for a condition for which it was not prescribed. Do not give it to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for more information about TOBI that is written for health professionals.

### **What are the ingredients in TOBI?**

**Active ingredient:** tobramycin

**Inactive ingredients:** sodium chloride in sterile water for injection, sulfuric acid, sodium hydroxide, and nitrogen

### **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.

Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936

For more information, go to [www.pharma.us.novartis.com](http://www.pharma.us.novartis.com) or call 1-888-669-6682.