

**Instructions for Use**  
**TOBI (TOH-bee)**  
**(tobramycin inhalation solution)**  
**for oral inhalation use**

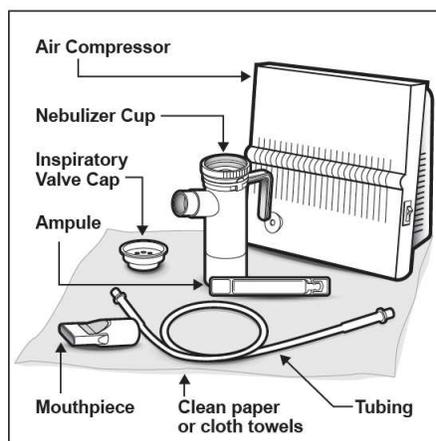
Read this Instructions for Use before you start using TOBI inhalation solution and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or treatment.

TOBI is made for inhalation using a PARI LC PLUS™ Reusable Nebulizer and a DeVilbiss® Pulmo-Aide® air compressor. TOBI can be taken at home, school, or at work. The following instructions tell you how to use the DeVilbiss Pulmo-Aide air compressor and PARI LC PLUS Reusable Nebulizer to administer TOBI.

**You will need the following supplies (See Figure A):**

- 1 TOBI plastic ampule (TOBI is packaged with 4 ampules in each foil pouch)
- DeVilbiss Pulmo-Aide air compressor
- PARI LC PLUS Reusable Nebulizer
- Tubing to connect the nebulizer and compressor
- Clean paper or cloth towels
- Nose clips (optional)

**(Figure A)**



It is important that your nebulizer and compressor function properly before starting your TOBI therapy.

Note: Read the manufacturer care and use instructions for important information.

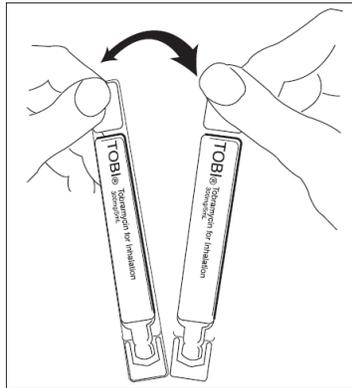
**Prepare Your TOBI for Inhalation Therapy**

**Step 1:** Wash your hands thoroughly with soap and water.

**Step 2:** Open the foil pouch.

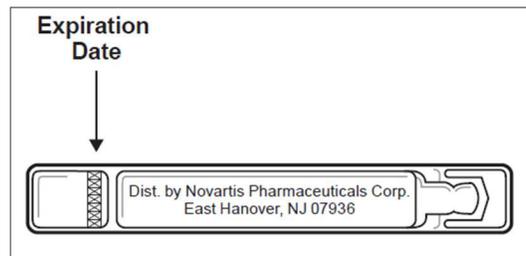
**Step 3:** Separate 1 TOBI ampule by gently pulling apart at the bottom tabs (See **Figure B**). Place the remaining TOBI ampules in the refrigerator.

(Figure B)



**Step 4:** Check the expiration date stamped on the TOBI ampule (See **Figure C**). **Do not** use the TOBI ampule if the expiration date has passed.

(Figure C)



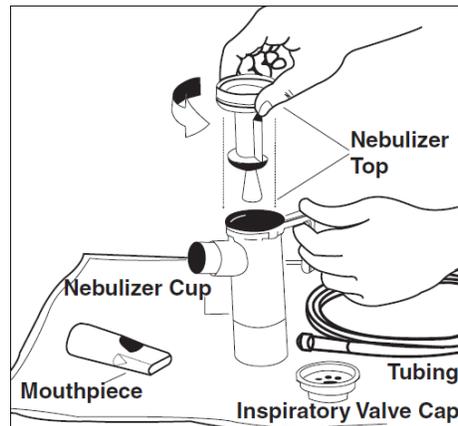
**Step 5:** Check that the TOBI ampule medicine is clear and does not have particles.

- Unrefrigerated TOBI, which is normally slightly yellow, may darken with age. This color change does not mean there is any change in the quality of the medicine.
- **Do not** use the TOBI ampule if the medicine is cloudy or has particles.
- Throw it away and get a new one.

**Step 6:** Lay out the parts of a PARI LC PLUS Reusable Nebulizer package on a clean, dry paper or cloth towel. You should have the following parts (**See Figure D**):

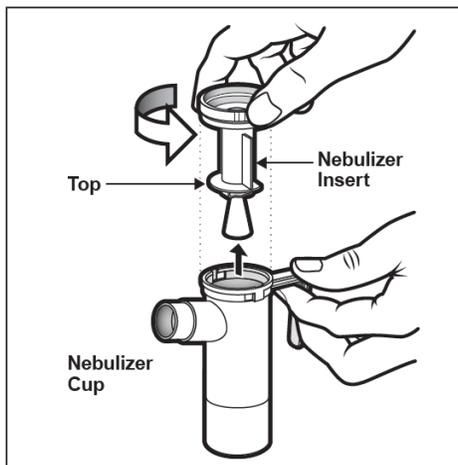
- Nebulizer Top and Bottom (Nebulizer Cup) Assembly
- Inspiratory Valve Cap
- Mouthpiece with Valve
- Tubing

(Figure D)



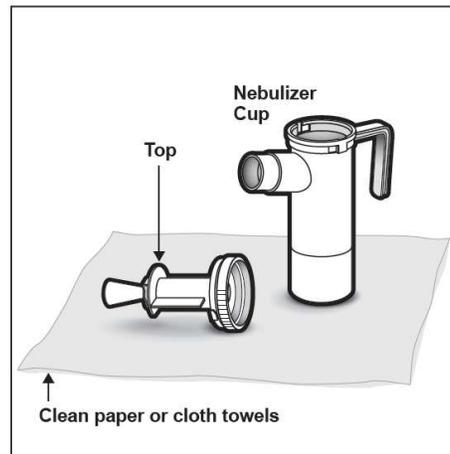
**Step 7:** Remove the Nebulizer Top from the Nebulizer Cup by twisting the Nebulizer Top counter-clockwise, and then lifting off (**See Figure E**).

(Figure E)



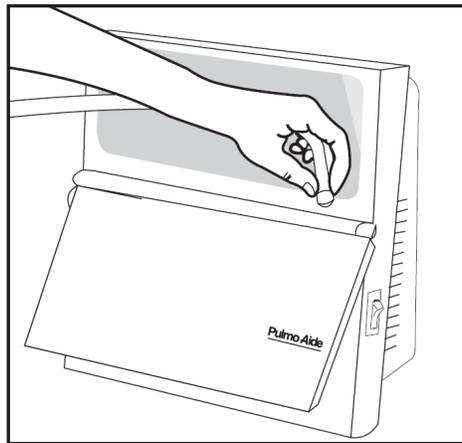
**Step 8:** Place the Nebulizer Top on the clean paper or cloth towel by standing the Nebulizer Cup upright on the towel (See Figure F).

(Figure F)



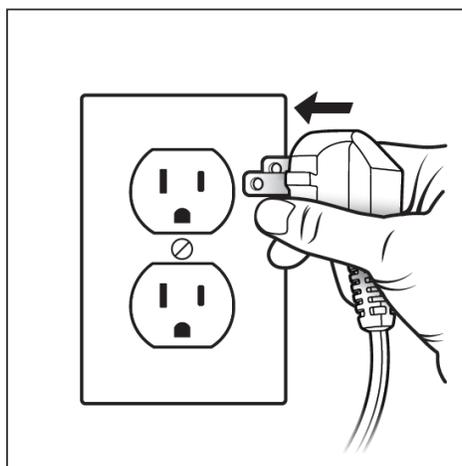
**Step 9:** Connect one end of the tubing to the compressor air outlet (See Figure G). The tubing should fit tightly.

(Figure G)



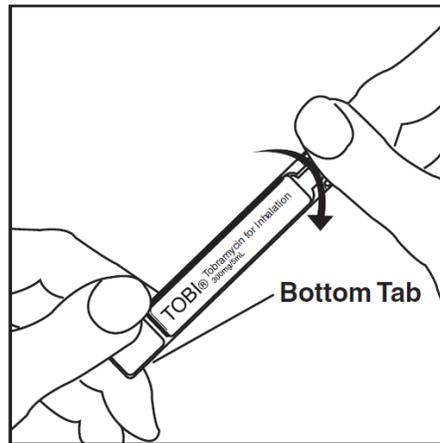
**Step 10:** Plug in your compressor to an electrical outlet (See Figure H).

(Figure H)



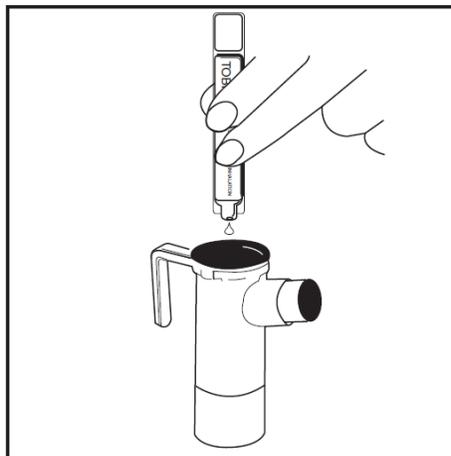
**Step 11:** Open the TOBI ampule by holding the bottom tab with 1 hand and twisting off the top of the TOBI ampule with the other hand (See **Figure I**). Be careful not to squeeze the TOBI ampule until you are ready to empty all the medicine into the Nebulizer Cup.

(Figure I)



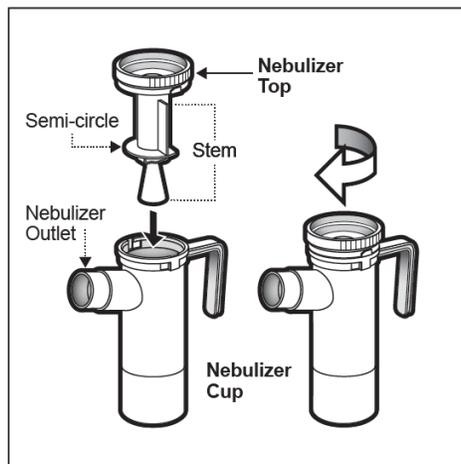
**Step 12:** Squeeze all the medicine of the TOBI ampule into the Nebulizer Cup (See **Figure J**).

(Figure J)



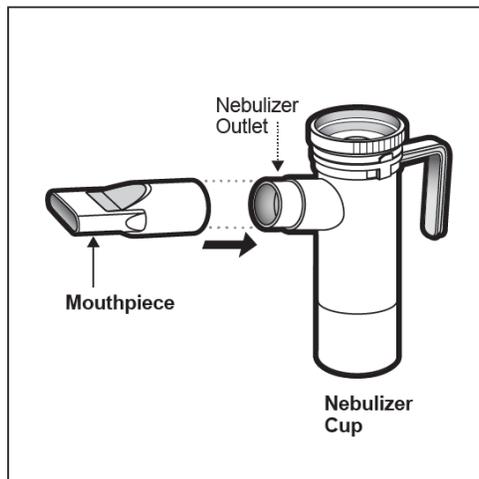
**Step 13:** Replace the Nebulizer Top. To replace the Nebulizer Top insert the Nebulizer Top into the Nebulizer Cup with the semi-circle halfway down the stem of the Nebulizer Top facing the Nebulizer Outlet. Turn the Nebulizer Top clockwise until securely fastened to the nebulizer Cup. (See **Figure K**).

(Figure K)



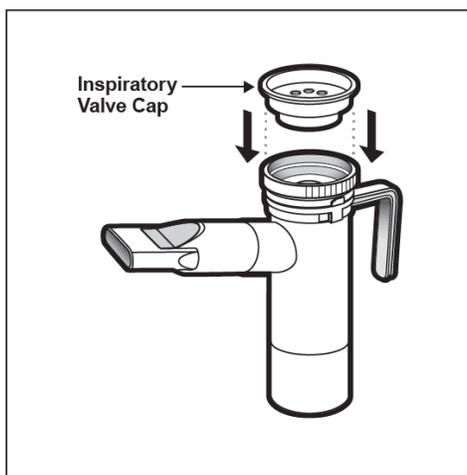
**Step 14:** Push the Mouthpiece straight onto the Nebulizer Outlet (See Figure L).

(Figure L)



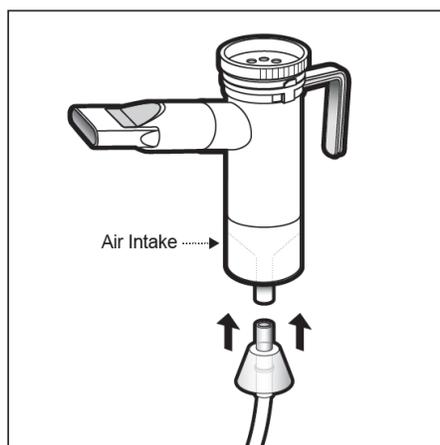
**Step 15:** Firmly push the Inspiratory Valve Cap straight down onto the Nebulizer Top (See Figure M). The Inspiratory Valve Cap will fit tightly.

(Figure M)



**Step 16:** Hold the Nebulizer Cup upright and firmly push the free end of the tubing from the compressor to the Air Intake on the bottom of the Nebulizer Cup (See Figure N). Make sure to keep the Nebulizer Cup upright.

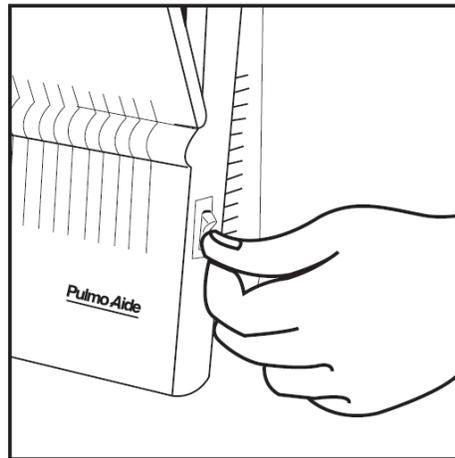
(Figure N)



## Giving your TOBI Inhalation Therapy

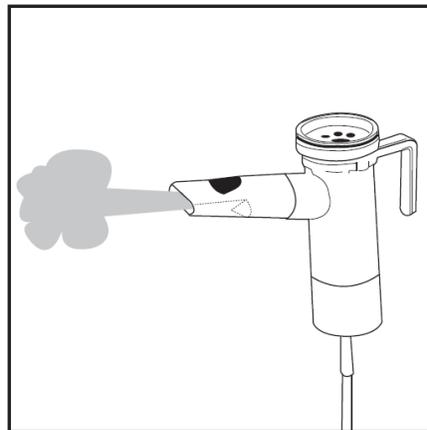
**Step 17:** Turn on the compressor (See **Figure O**).

(**Figure O**)



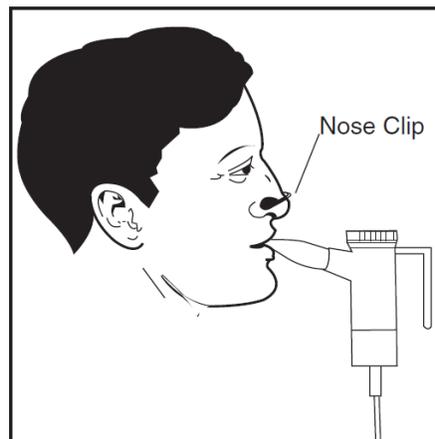
**Step 18:** Check for a steady mist from the Mouthpiece (See **Figure P**). If there is no mist, check all tubing connections and make sure that the compressor is working properly.

(**Figure P**)



**Step 19:** Sit or stand in an upright position that will allow you to breathe normally. Place the Mouthpiece between your teeth and on top of your tongue and breathe normally only through your mouth (See **Figure Q**). Nose clips may help you breathe through your mouth and not through your nose. **Do not** block the airflow with your tongue.

(**Figure Q**)



**Step 20:** Keep breathing in your TOBI medicine for at least 15 minutes to get your full dose. Continue therapy until all your TOBI medicine is gone, and there is no longer any mist being made. You may hear a sputtering sound coming from the Mouthpiece when the Nebulizer Cup is empty. The entire TOBI therapy should take about 15 minutes to complete.

If you are interrupted, need to cough or rest during your TOBI treatment, turn off the compressor to save your medicine. Turn the compressor back on when you are ready to restart your treatment.

Follow the nebulizer cleaning and disinfecting instructions after completing your therapy.

### **After your TOBI Inhalation Therapy**

#### **Cleaning Your Nebulizer**

To reduce the risk of infection, illness or injury from contamination, you must thoroughly clean all parts of the nebulizer as instructed after each treatment. Never use a nebulizer with a clogged nozzle. If the nozzle is clogged, no aerosol mist is made, and your therapy will not be as effective. Replace the nebulizer if clogging occurs.

- 1) Remove tubing from nebulizer and disassemble nebulizer parts.
- 2) Wash all parts (except tubing) with warm water and liquid dish soap.
- 3) Rinse thoroughly with warm water and shake out water.
- 4) Air dry or hand dry nebulizer parts on a clean, lint-free cloth. Reassemble nebulizer when dry, and store.

You can also wash all parts of the nebulizer in a dishwasher (except tubing).

- 1) Place the nebulizer parts in a dishwasher basket.
- 2) Place the dishwasher basket on the top rack of the dishwasher.
- 3) Remove and dry the parts when the cycle is complete.

#### **Disinfecting Your Nebulizer**

Your nebulizer is for your use only. **Do not** share your nebulizer with other people. You must disinfect the nebulizer every other treatment day. Failure to disinfect the nebulizer every other treatment day could lead to serious or fatal illness.

Clean the nebulizer as described above. Every other treatment day, disinfect the nebulizer parts (except tubing) by boiling them in water for a full 10 minutes. Dry parts on a clean, lint-free cloth.

#### **Care and Use of Your Pulmo-Aide Compressor**

Follow the manufacturer instructions for care and use of your compressor.

#### **Filter Change:**

- DeVilbiss Compressor filters should be changed every 6 months or sooner if the filter turns completely gray in color.

#### **Compressor Cleaning:**

- With power switch in the “Off” position, unplug power cord from wall outlet.
- Wipe outside of the compressor cabinet with a clean, damp cloth every few days to keep dust free.

Caution: **Do not** submerge in water because this will damage the compressor.

#### **How should I store TOBI?**

- Store TOBI ampules in a refrigerator between 36°F to 46°F (2°C to 8°C) until needed.
- You may store the TOBI ampules in the foil pouches (opened or unopened) at room temperature 77°F (25°C) for up to 28 days.
- **Do not** use TOBI ampules if they have been stored at room temperature for more than 28 days.
- Protect TOBI ampules from light.

#### **Keep TOBI and all medicines out of the reach of children.**

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

**Additional Information**

Nebulizer: 1-800-327-8632

Compressor: 1-800-338-1988

TOBI: 1-888-NOW-NOVA (1-888-669-6682)

Distributed by:

Novartis Pharmaceuticals Corporation

East Hanover, New Jersey 07936

© Novartis

IFU:TOBRIS:RX

12/2018