

**INSTRUCTIONS FOR USE**  
**OHTUVAYRE (OH-too-vare)**  
**(ensifentrine)**  
**inhalation suspension, for oral inhalation**

This Instructions for Use contains information on how to use OHTUVAYRE.



**OHTUVAYRE**  
**single-dose ampule**

**To use OHTUVAYRE, you will also need a jet nebulizer machine and air compressor.**

**Important Information You Need to Know Before Using OHTUVAYRE**

- **For oral inhalation only**
- **OHTUVAYRE is used only in a standard jet nebulizer machine** with a mouthpiece connected to an air compressor.
- **Do not mix** other medicines with OHTUVAYRE in your nebulizer.
- OHTUVAYRE comes in an ampule that is sealed in a foil pouch. Do not open the sealed pouch until you are ready to use a dose of OHTUVAYRE.
- **Use your OHTUVAYRE right away after opening.** For pouches of 5 ampules, place the remaining ampules back into the pouch until next use.
- Throw away the OHTUVAYRE ampules immediately after use. Due to their small size, the ampules pose a danger of choking to young children.

**Preparing to Use OHTUVAYRE**

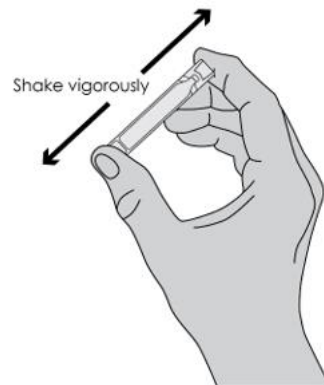
- Make sure you know how to use your nebulizer machine before you use it to breathe in OHTUVAYRE.
- Read the following steps before using OHTUVAYRE. If you have any questions, ask your healthcare provider or pharmacist.

**Using OHTUVAYRE**

**Step 1. Open Pouch:** Open the foil pouch by tearing along the seam of the pouch. Remove an ampule of OHTUVAYRE from the foil pouch. For pouches of 5 ampules, remove one ampule and place the remaining ampules back into the pouch until next use.

**Step 2. Shake Ampule:** Shake ampule vigorously until the contents are thoroughly mixed (see **Figure A**). The contents will appear cloudy and yellow to pale yellow in color.

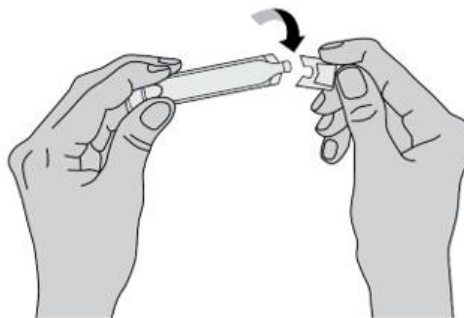
**Figure A**



**Step 3. Open Ampule:** Carefully twist open the top of the ampule and use the contents right away (see **Figure B**).

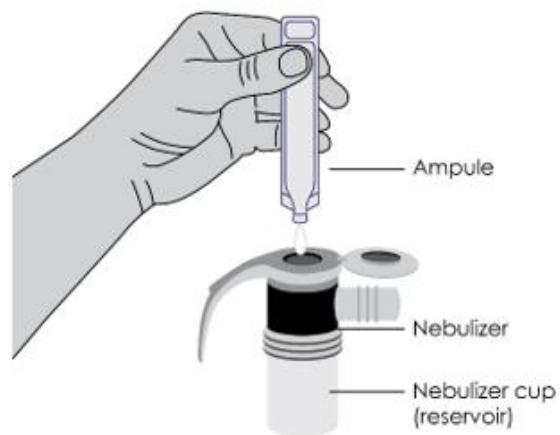
**Figure B**

Twist open the top of the ampule.



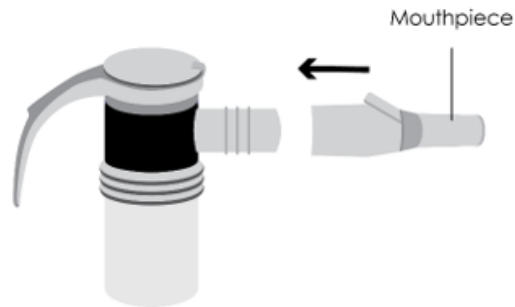
**Step 4. Add Medicine:** Squeeze all the medicine from the ampule into the nebulizer cup (reservoir) (see **Figure C**).

**Figure C**



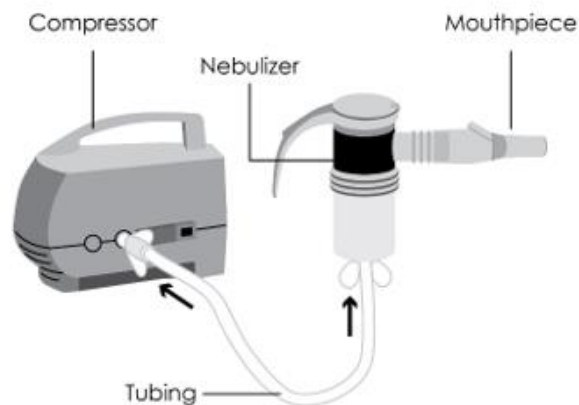
**Step 5. Attach Mouthpiece:** If a separate mouthpiece attachment is supplied with your nebulizer, connect the mouthpiece to the nebulizer (see **Figure D**).

**Figure D**



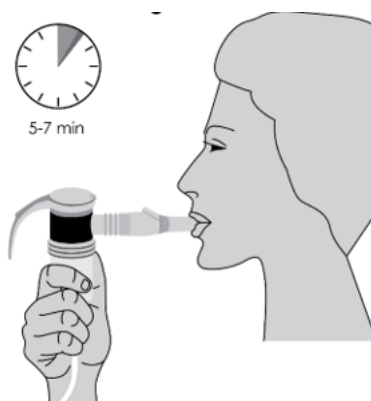
**Step 6. Connect the Nebulizer to the Compressor:** Firmly insert one end of the tubing to the compressor. Insert the other end of the tubing to the bottom of the nebulizer cup (reservoir) (see **Figure E**).

**Figure E**



**Step 7. Prepare for Treatment:** Sit in a comfortable, upright position. Place the mouthpiece in your mouth and close your lips around the mouthpiece (see **Figure F**).

**Figure F**



**Step 8. Begin Treatment:** Turn on the compressor to begin treatment.

**Step 9. Breathe in Medicine:** Breathe calmly, deeply, and evenly as possible until no more mist is seen in the nebulizer reservoir. Your treatment will typically take about 5 to 7 minutes. When you no longer see any mist in the nebulizer, your treatment is completed. Turn the compressor **off**.

#### **Storing OHTUVAYRE and Nebulizer**

- Clean and store your nebulizer. See the manufacturer's instructions that come with your nebulizer for how to clean and store your nebulizer.
- Store OHTUVAYRE ampules in the protective foil pouch in the carton at room temperature between 68°F to 77°F (20°C to 25°C) away from direct sunlight and excessive heat, in an upright position as indicated on the carton. Do not freeze.

#### **Additional Information**

Please call Verona Pharma at 1-888-672-0371 for more product information or to report problems with the product. Please call Verona Pharma at 1-888-672-0371 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch) to report adverse reactions.

Manufactured for: Verona Pharma, Inc., Raleigh, NC 27615

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

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