

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

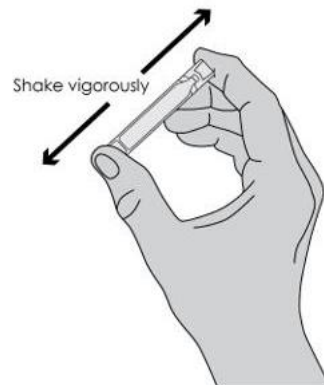
- Make sure you know how to use your nebulizer machine before you use it to breathe in OHTUVAYRE.
- Read the following steps before using OHTUVAYRE. If you have any questions, ask your healthcare provider or pharmacist.

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.

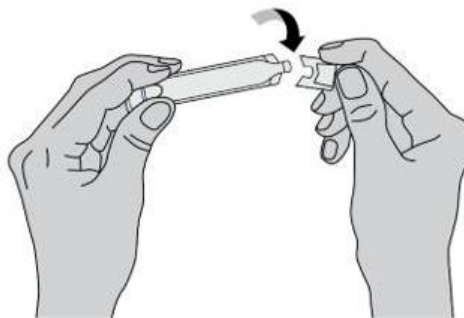
Figure A



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

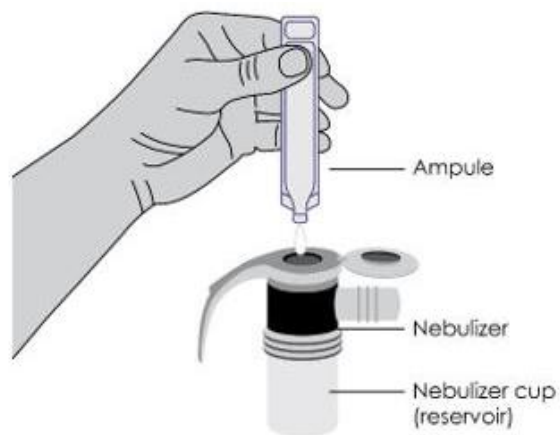
Figure B

Twist open the top of the ampule.



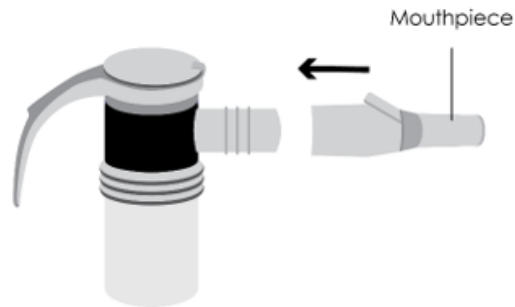
Step 4. Add Medicine: Squeeze all the medicine from the ampule into the nebulizer cup (reservoir) (see **Figure C**).

Figure C



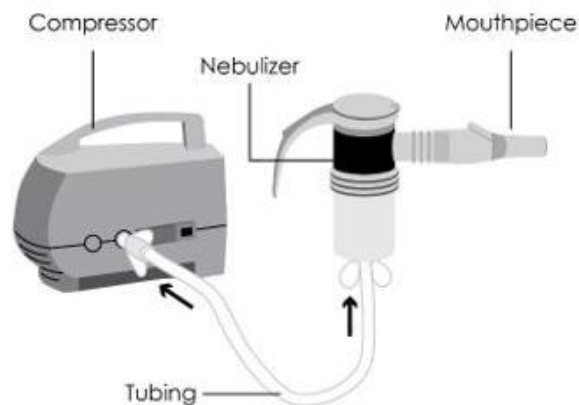
Step 5. Attach Mouthpiece: If a separate mouthpiece attachment is supplied with your nebulizer, connect the mouthpiece to the nebulizer (see **Figure D**).

Figure D



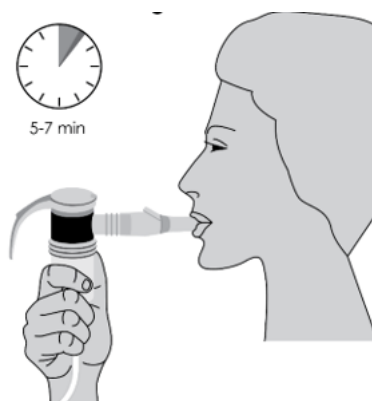
Step 6. Connect the Nebulizer to the Compressor: Firmly insert one end of the tubing to the compressor. Insert the other end of the tubing to the bottom of the nebulizer cup (reservoir) (see **Figure E**).

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 Merck Sharp & Dohme LLC at 1-800-672-6372 for more product information or to report problems with the product. Please call Merck Sharp & Dohme LLC at 1-800-672-6372 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch to report adverse reactions.

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For patent information: www.msd.com/research/patent

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

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