

FOR PATIENTS WITH COPD

How to Take OHTUVAYRE

INDICATION

OHTUVAYRE® (ensifentrine) is a prescription medicine used to treat chronic obstructive pulmonary disease (COPD) in adults. COPD is a chronic (long-term) lung disease that includes chronic bronchitis, emphysema, or both.

SELECT SAFETY INFORMATION

What is the most important information I should know about OHTUVAYRE?

OHTUVAYRE can cause serious side effects, including:

- Sudden breathing problems immediately after inhaling your medicine.
If you have sudden breathing problems immediately after inhaling your medicine, stop using OHTUVAYRE and call your healthcare provider right away or go to the nearest hospital emergency room right away.

Select Safety Information continues on next page.

Instructions for Use

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.

SELECT SAFETY INFORMATION (cont'd)

- Mental health problems including suicidal thoughts and behavior. You may experience mood or behavior changes when taking OHTUVAYRE. Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you: thoughts of suicide or dying, attempt to commit suicide, trouble sleeping (insomnia), new or worse anxiety, new or worse depression, acting on dangerous impulses, and/or other unusual changes in your behavior or mood.

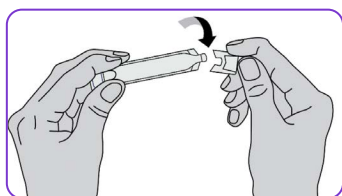
Step 1: Open Pouch

Open the pouch by tearing along the seam. Remove the 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. Use your OHTUVAYRE right away after opening.



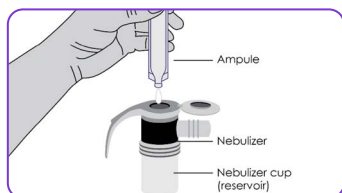
Step 2: Shake Ampule

Shake the ampule vigorously until all contents are thoroughly mixed. The contents will appear cloudy and yellow to pale yellow in color.



Step 3: Open Ampule

Carefully twist the top of the ampule to open. Use the contents right away.



Step 4: Add Medicine

Squeeze all the medicine from the ampule into the nebulizer cup (reservoir). **Do not mix** other medicines with OHTUVAYRE in your nebulizer.

Throw away the OHTUVAYRE ampules immediately after use. Due to their small size, the ampules pose a danger of choking to young children.

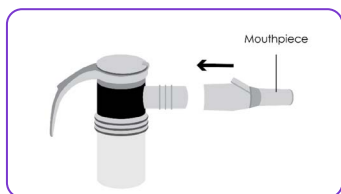
SELECT SAFETY INFORMATION (cont'd)

Do not use OHTUVAYRE to treat sudden breathing problems. Always have a rescue inhaler with you.

Who should not use OHTUVAYRE?

Do not use OHTUVAYRE if you have had an allergic reaction to ensifentrine or any of the ingredients in OHTUVAYRE.

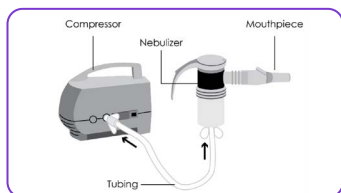
Select Safety Information continues on next page.



Step 5: Attach Mouthpiece

If a separate mouthpiece attachment was provided with your nebulizer, attach it now.

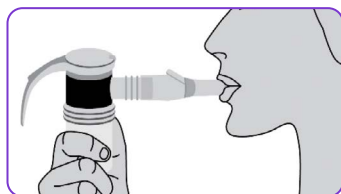
Note: Please refer to the instructions that came with your nebulizer.



Step 6: Connect Nebulizer to Compressor

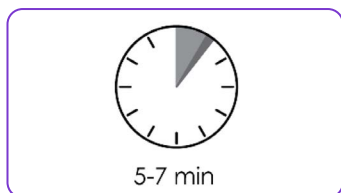
Firmly insert one end of the tubing into the compressor. Insert the other end into the bottom of the nebulizer cup (reservoir).

Note: Please refer to your nebulizer manual for specifics on connecting to your compressor.



Step 7: Prepare for Treatment

Sit in a comfortable, upright position. Place the mouthpiece in your mouth and close your lips around it.



Step 8: Begin Treatment

Turn on the compressor to begin treatment.

SELECT SAFETY INFORMATION (*cont'd*)

What should I tell my healthcare provider before using OHTUVAYRE?

- Before you use OHTUVAYRE, tell your healthcare provider if you have or have had a history of mental health problems including depression and suicidal behavior; have liver problems; are pregnant or plan to become pregnant; or are breastfeeding. It is not known if OHTUVAYRE may harm your unborn baby. It is not known if the medicine in OHTUVAYRE passes into your breast milk and if it can harm your baby.

Select Safety Information continues on next page.

Step 9: Breathe in Medicine

Breathe calmly, deeply, and as 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® (ensifentrine) 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 (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.

Refer to your nebulizer's product manual and Specialty Pharmacy for specific maintenance instructions. Talk to your doctor if you have any specific questions about your dosage.

SELECT SAFETY INFORMATION (*cont'd*)

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

What are the most common side effects of OHTUVAYRE?

The most common side effects of OHTUVAYRE include back pain, high blood pressure, bladder infection, and diarrhea.

These are not all the possible side effects of OHTUVAYRE. Call your doctor for medical advice about side effects.

Select Safety Information continues on next page.

SELECT SAFETY INFORMATION (*cont'd*)

How should I use OHTUVAYRE?

- OHTUVAYRE is only for use with a nebulizer.
- Do not use OHTUVAYRE unless your healthcare provider has taught you how to use it with your nebulizer and you understand how to use it correctly.
- Use OHTUVAYRE exactly as your healthcare provider tells you to use it. Do not use OHTUVAYRE more often than prescribed.
- OHTUVAYRE is taken as a breathing treatment by oral (mouth) inhalation and should be used with a standard jet nebulizer with a mouthpiece connected to an air compressor.
- Do not mix other medicines with OHTUVAYRE in your nebulizer.

This summary does not include all the information about OHTUVAYRE and is not meant to take the place of a discussion with your healthcare provider about your treatment. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please read the accompanying Patient Information and Instructions for Use for OHTUVAYRE, and discuss them with your doctor. The physician Prescribing Information also is available.

