FOR COPD MAINTENANCE IN ADULTS

Ohtuvayre™
(ensifentrine) Inhalation Suspension
3 mg/2.5 mL

Recommended in the 2025 GOLD Report

The GOLD Report now includes Ohtuvayre in the follow-up treatment algorithm for patients experiencing persistent dyspnea, acknowledging the following benefits[1]:

- A novel first-in-class inhaled dual inhibitor of PDE3 and PDE4, combining anti-inflammatory activity with bronchodilator effects
- Significantly improves lung function **(Evidence A)** and dyspnea **(Evidence A)**

PDE3 = phosphodiesterase 3; PDE4 = phosphodiesterase 4.

Important Safety Information & Indication

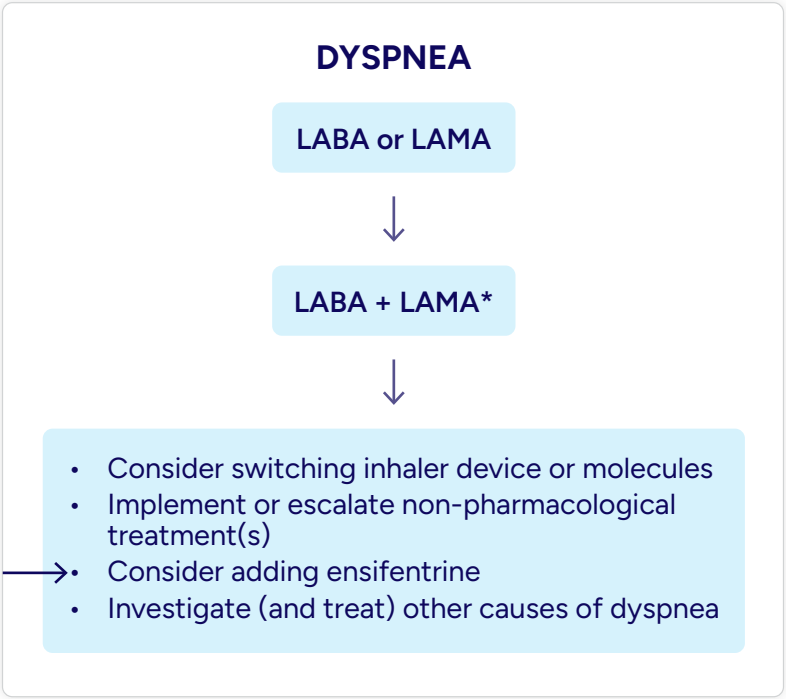
IMPORTANT SAFETY INFORMATION

Contraindication: Ohtuvayre is contraindicated in patients with hypersensitivity to ensifentrine or any component of this product.

Warnings and Precautions:

Acute Episodes of Bronchospasm Ohtuvayre should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled, short-acting bronchodilator.

2025 GOLD Report Follow-Up Pharmacological Treatment



Read the full report.

*Single inhaler therapy may be more convenient and effective than multiple inhalers; single inhalers improve adherence to treatment.

GOLD = Global Initiative for Chronic Obstructive Lung Disease; LABA = long-acting beta2-agonist; LAMA = long-acting muscarinic antagonist.

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EFFICACY & SAFETY

Proven to be efficacious and well tolerated for symptomatic patients

Ohtuvayre™ demonstrated a significant improvement in lung function at Week 12.[2,3]*

- Patients experienced better breathing as early as Day 1.

Most common adverse reactions with an incidence rate of ≥1% and greater than placebo included back pain, hypertension, urinary tract infection, and diarrhea.[2]

Ohtuvayre combines the benefits of non-steroidal anti-inflammatory and bronchodilator effects for patients experiencing persistent symptoms, and may be added to other maintenance therapies.[2-5]

*Ohtuvayre was studied in two 24-week, randomized, double-blind, placebo-controlled studies in patients with moderate to severe COPD (N=1553). Primary endpoint: change from baseline in FEV_1 AUC_{0-12h} at Week 12. Secondary endpoint: Peak FEV_1 at Week 12; Day 1 was not included in the statistical hierarchy.[2,3]

IMPORTANT SAFETY INFORMATION (cont'd)

Paradoxical Bronchospasm As with other inhaled medicines, Ohtuvayre may produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs following dosing with Ohtuvayre, it should be treated immediately with an inhaled, short-acting bronchodilator. Ohtuvayre should be discontinued immediately and alternative therapy should be instituted.

Please see Full Important Safety Information throughout and Full Prescribing Information **also available on** OhtuvayreHCP.com**.**

PATIENT AND OFFICE SUPPORT

Prescribe through Verona Pathway Plus™

Prescribe directly through Verona Pathway Plus to access our Specialty Pharmacy Network and receive coverage and affordability support for your patients.

Step 1

Complete the Ohtuvayre Prescription and Patient Consent Form, found on **OhtuvayreHCP.com**

Step 2

Fax both forms to **833-392-8999**

For more information call Verona Pathway Plus at 833-372-8492.

Interested in Prescribing? Scan or click here to access the prescription form and other available resources, or reach out to your representative.

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IMPORTANT SAFETY INFORMATION (cont'd)

Psychiatric Events Including Suicidality Before initiating treatment with Ohtuvayre, healthcare providers should carefully weigh the risk and benefits of treatment with Ohtuvayre in patients with a history of depression and/or suicidal thoughts or behavior. Patients, their caregivers, and families should be advised of the need to be alert for the emergence or worsening of insomnia, anxiety, depression, suicidal thoughts, or other mood changes, and if such changes occur to contact their healthcare provider. Healthcare providers should carefully evaluate the risks and benefits of continuing treatment with Ohtuvayre if such events occur.

Treatment with Ohtuvayre is associated with an increase in psychiatric adverse reactions. Psychiatric events including suicide-related adverse reactions were reported in clinical studies in patients who received Ohtuvayre (1 suicide attempt and 1 suicide). Additionally, the most commonly reported psychiatric adverse reactions in the pooled 24-week safety population were insomnia (6 patients [0.6%] Ohtuvayre 3 mg; 2 patients [0.3%] placebo), and anxiety (2 patients [0.2%] Ohtuvayre 3 mg; 1 patient [0.2%] placebo). Depression-related reactions including depression, major depression, and adjustment disorder with depressed mood occurred in 4 patients [0.4%] receiving Ohtuvayre and no patients receiving placebo.

Please see Full Important Safety Information throughout and Full Prescribing Information **also available on** OhtuvayreHCP.com**.**

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IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions: The most common adverse reactions ≥1% in Ohtuvayre and greater than placebo in the pooled population were back pain 1.8%, hypertension 1.7%, urinary tract infection 1.3%, and diarrhea 1.0%.

These are not all of the possible risks associated with Ohtuvayre. **Please see the Full Prescribing Information for Ohtuvayre.**

To report suspected adverse reactions, contact Verona Pharma, Inc. at 1-888-672-0371 **or FDA at** 1-800-FDA-1088 **or** www.fda.gov/medwatch**.**

INDICATION

Ohtuvayre is indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients.

References: 1. Global Initiative for Chronic Obstructive Lung Disease. *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. (2025 Report)*. Global Initiative for Chronic Obstructive Lung Disease; 2024. **2.** Ohtuvayre™ (ensifentrine). Prescribing Information. Raleigh, NC: Verona Pharma plc; 2024. **3.** Anzueto A, Barjaktarevic IZ, Siler TM, et al. Ensifentrine, a novel phosphodiesterase 3 and 4 inhibitor for the treatment of chronic obstructive pulmonary disease: randomized, double-blind, placebo-controlled, multicenter phase III trials (the ENHANCE Trials). *Am J Respir Crit Care Med.* 2023;208(4):406-416. **4.** Boswell-Smith V, Spina D, Oxford AW, Comer MB, Seeds EA, Page CP. The pharmacology of two novel long-acting phosphodiesterase 3/4 inhibitors, RPL554 [9,10-dimethoxy-2(2,4,6-trimethylphenylimino)-3-(N-carbamoyl-2-aminoethyl)-3,4,6,7-tetrahydro-2H-pyrimido[6,1-a]isoquinolin-4-one] and RPL565 [6,7-dihydro-2-(2,6-diisopropylphenoxy)-9,10-dimethoxy-4H-pyrimido[6,1-a]isoquinolin-4-one]. *J Pharmacol Exp Ther.* 2006;318(2):840-848. **5.** Singh D, Martinez FJ, Watz H, Bengtsson T, Maurer BT. A dose-ranging study of the inhaled dual phosphodiesterase 3 and 4 inhibitor ensifentrine in COPD. *Respir Res.* 2020;21(1):47.

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