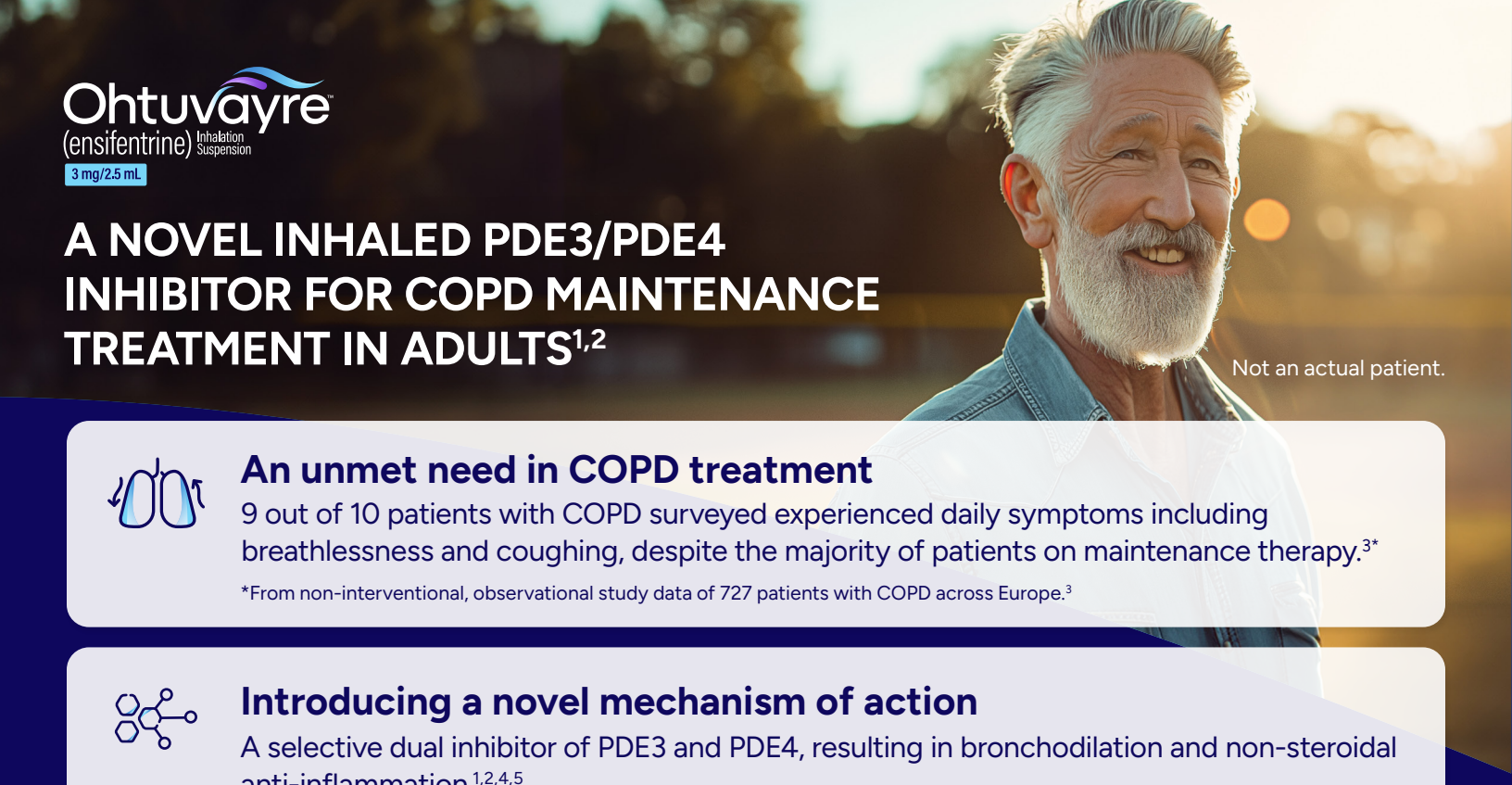
Ohtuvayre™
(ensifentrine) Inhalation Suspension
3 mg/2.5 mL

A NOVEL INHALED PDE3/PDE4 INHIBITOR FOR COPD MAINTENANCE TREATMENT IN ADULTS[1,2]


Not an actual patient.

An unmet need in COPD treatment

9 out of 10 patients with COPD surveyed experienced daily symptoms including breathlessness and coughing, despite the majority of patients on maintenance therapy.[3*]

*From non-interventional, observational study data of 727 patients with COPD across Europe.[3]

Introducing a novel mechanism of action

A selective dual inhibitor of PDE3 and PDE4, resulting in bronchodilation and non-steroidal anti-inflammation.[1,2,4,5]

Proven to be efficacious and well tolerated

Ohtuvayre™ demonstrated a significant improvement in lung function at Week 12.[1,2*] Most common adverse reactions with an incidence rate of ≥1% and greater than placebo included back pain, hypertension, urinary tract infection, and diarrhea.[1]

*Ohtuvayre was studied in two 24-week, randomized, double-blind, placebo-controlled studies in patients with moderate to severe COPD (N=1553).[1]

Appropriate for a broad population of patients with COPD

An appropriate treatment option for multiple patient types, including those who are symptomatic on maintenance therapy.[1,2]

Prescribe exclusively through Verona Pathway Plus™

Access Ohtuvayre through Verona Pathway Plus and our Durable Medical Equipment Accredited Specialty Pharmacy network. Coverage and support services are available for you and your patients through our experienced team of Care Coordinators.

Indication and Important Safety Information

INDICATION

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

IMPORTANT SAFETY INFORMATION

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

Please see continued Important Safety Information on the following page and the Full Prescribing Information for Ohtuvayre, also available at OhtuvayreHCP.com.

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For more information about Ohtuvayre, visit OhtuvayreHCP.com.

IMPORTANT SAFETY INFORMATION (continued)

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.

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.

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.

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.

References: 1. Ohtuvayre™ (ensifentrine). Prescribing Information. Raleigh, NC: Verona Pharma plc; 2024. **2.** 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. **3.** Miravitlles M, Worth H, Soler Cataluña JJ, et al. Observational study to characterise 24-hour COPD symptoms and their relationship with patient-reported outcomes: results from the ASSESS study. *Respir Res.* 2014;15(1):122. **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;21:47.

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