

Fluticasone Furoate INN, Umeclidinium Bromide INN and Vilanterol Trifenatate INN (Rotacap)

Composition

**Trihale 100:** Each capsule contains Fluticasone Furoate INN 100 mcg, Umeclidinium Bromide INN equivalent to 62.5 mcg of Umeclidinium and Vilanterol Trifenatate INN equivalent to 25 mcg of Vilanterol.

**Trihale 200:** Each capsule contains Fluticasone Furoate INN 200 mcg, Umeclidinium Bromide INN equivalent to 62.5 mcg of Umeclidinium and Vilanterol Trifenatate INN equivalent to 25 mcg of Vilanterol.

Pharmacology

**Trihale** represent 3 different classes of medications (an Inhaled Corticosteroid, a LAMA, and a LABA), each having different effects. Fluticasone Furoate is a synthetic trifluorinated corticosteroid with potent anti-inflammatory activity. Umeclidinium is a long-acting muscarinic antagonist (LAMA). In the airways, it exhibits pharmacological effects through inhibition of M3 receptor at the smooth muscle leading to bronchodilation. Vilanterol is a LABA (Long Acting Beta<sub>2</sub> Agonist) which relaxes airway smooth muscle by stimulating β<sub>2</sub>-adrenergic receptors causing bronchodilation.

Indication

**Trihale** is indicated for the maintenance treatment of patients with Asthma & Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and/or emphysema.

Dosage and Administration

Route of Administration: Inhalation Capsule

The capsules are intended for use with **ACME's Easyhaler**. While using with the **ACME's Easyhaler**, the capsules will be pierced and will be ready to use.

18 years and older

**Trihale 100:** One Rotacap once daily.

**Trihale 200:** One Rotacap once daily.

**Trihale** should be used at the same time every day. Do not use **Trihale** more than 1 time in every 24 hours.

OR AS DIRECTED BY THE PHYSICIAN.

Contraindication

The use of **Trihale** is contraindicated in:

- Patients with severe hypersensitivity to milk proteins.
- Those who have demonstrated hypersensitivity to Fluticasone Furoate, Umeclidinium, Vilanterol or any of the excipients.

Warning and Precautions

Patients should be instructed in the proper use of **ACME's Easyhaler** to ensure that the drug reaches the target areas within the lungs. A capsule should only be instructed into the **ACME's Easyhaler** immediately prior to use. It may be helpful to rinse out the mouth with water immediately after inhalation.

**Trihale** should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. Patients who have been taking oral or inhaled, short-acting beta<sub>2</sub>-agonists on a regular basis (e.g., 4 times a day) should be instructed to discontinue the regular use of these drugs after starting of **Trihale**.

Side Effects

Headache, Nausea, Vomiting, Diarrhea, Back pain, Cough, Taste disturbance, Mouth and/or throat pain.

Use in Pregnancy and Lactation

There are insufficient data on the use of **Trihale** in pregnant women. There is no information of **Trihale** presence in human milk and the effects on the breastfed child.

Use in Children and Adolescents

**Trihale** is not indicated for children. The safety and efficacy in pediatric patients have not been established. **Trihale** is not indicated under 18 years of age.

Drug Interaction

NIInhibitors of Cytochrome P450 3A4, Monoamine Oxidase Inhibitors and Tricyclic Antidepressants, Beta-adrenergic Receptor Blocking Agents, Non–Potassium-Sparing Diuretics and Anticholinergics.

Overdose

Overdose symptoms may include chest pain, fast heart rate, and feeling shaky or short of breath.

Storage

Store below 25°C temperature & dry place, protected from light.

Keep all medicines out of reach of children.

Packing

**Trihale 100:** Each box contains 1X10 capsules in Alu-Alu blister for use with **ACME's Easyhaler** device.

**Trihale 100:** Each box contains 3X10 capsules in Alu-Alu blister with free **ACME's Easyhaler**.

**Trihale 200:** Each box contains 1X10 capsules in Alu-Alu blister for use with **ACME's Easyhaler** device.

**Trihale 200:** Each box contains 3X10 capsules in Alu-Alu blister with free **ACME's Easyhaler**.

Pharmaceutical Precautions

- Rotacap is to be used through **Easyhaler**.
- Rotacap is not to be swallowed.
- Do not exceed the recommended dose.
- Insert the Rotacap in the **Easyhaler** just prior to use, as Rotacap exposed to moisture may not be pierced easily.

\*Further information is available in request.