

# Triflo Arocap

Fluticasone Furoate 100 mcg, Umeclidinium 62.5 mcg and Vilanterol 25 mcg

## COMPOSITION

**Triflo Arocap Capsule:** Each inhalation capsule contains Fluticasone Furoate INN 100 mcg, Umeclidinium 62.5 mcg (as Umeclidinium Bromide INN) and Vilanterol 25 mcg (as Vilanterol Trifenatate INN).

## PHARMACOLOGY

Triflo Arocap is a dry powder inhalation capsule that contains a combination of Fluticasone Furoate, an inhaled corticosteroid (ICS); umeclidinium, an anticholinergic; and Vilanterol, a long-acting beta2-adrenergic agonist (LABA) which are different classes of medications & each having different effects on clinical and physiological indices.

Fluticasone Furoate is a synthetic corticosteroid with anti-inflammatory activity. Inflammation is an important component in the pathogenesis of COPD and asthma. Fluticasone furoate has been shown to have a wide range of actions on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) who are involved in inflammation.

Umeclidinium is a long-acting muscarinic antagonist, which is often referred to as an anticholinergic. It has a similar affinity to the subtypes of muscarinic receptors M1 to M5. In the airways, it exhibits pharmacological effects through inhibition of the M3 receptor in the smooth muscle leading to bronchodilation.

Vilanterol is a selective beta2-agonists that exerts its pharmacologic effects by stimulating intracellular adenylyl cyclase, the enzyme that catalyzes the conversion of adenosine triphosphate (ATP) to cyclic-3',5'-adenosine monophosphate (cyclic AMP). Increased cyclic AMP level causes relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.

## INDICATIONS

Triflo Arocap is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD) & the maintenance treatment of asthma in patients aged 18 years and older.

## DOSE & ADMINISTRATION

### Adults: 18 years & older

**Maintenance treatment of COPD:** 1 capsule of Triflo Arocap once daily should be administered by oral inhalation with the help of AroHaler device.

**Maintenance treatment of asthma:** 1 capsule of Triflo Arocap once daily should be administered by oral inhalation with the help of AroHaler device.

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

Limitations of use: Not indicated for relief of acute bronchospasm.

## CONTRAINDICATIONS

This combination is contraindicated in the following conditions:

- Primary treatment of status asthmaticus or other acute episodes of COPD where intensive measures are required.
- Severe hypersensitivity to any ingredients.

## WARNINGS & PRECAUTIONS

- Should not be used in combination with additional therapy containing a LABA because of the risk of overdose.
- *Candida albicans* infection of the mouth and pharynx may occur. Periodical monitoring is required. Need to rinse the mouth with water after inhalation to help reduce the risk.
- Patient monitoring for signs and symptoms of pneumonia is required as there is an increased risk of pneumonia in patients with COPD.
- Potential worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infections; ocular herpes simplex). Caution is advised in patients with these infections. A more serious or even fatal course of chickenpox or measles can occur in susceptible patients.
- Risk of impaired adrenal function when transferring from systemic corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to inhaled corticosteroids.
- Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue slowly.
- If paradoxical bronchospasm occurs, discontinue and institute alternative therapy.
- In patients with cardiovascular disorders cautious use is needed because of beta-adrenergic stimulation.
- Assessment is required for a decrease in bone mineral density initially and periodically thereafter.
- Glaucoma and cataracts may occur with long-term use of ICS. Worsening of narrow-angle glaucoma may occur. If symptoms occur in patients with narrow-angle glaucoma, need to contact a healthcare provider or an ophthalmologist immediately.
- Worsening of urinary retention may occur. If symptoms occur in patients with prostatic hyperplasia or bladder neck obstruction, need to contact a healthcare provider immediately.
- In patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis, it's important to use it cautiously
- Need to be alert for hypokalemia and hyperglycemia.

## SIDE EFFECTS

**COPD:** Common adverse reactions (incidence  $\geq 1\%$ ) are respiratory tract infection, pneumonia, bronchitis, oral candidiasis, headache, arthralgia, influenza, sinusitis, pharyngitis, rhinitis, constipation, urinary tract infection, diarrhea, gastroenteritis, oropharyngeal pain, cough, and dysphonia.

**Asthma:** Common adverse reactions (incidence  $\geq 2\%$ ) are pharyngitis/nasopharyngitis, respiratory tract infection, bronchitis, sinusitis, urinary tract infection, rhinitis, influenza, and headache.

## USE IN SPECIFIC POPULATIONS

**Use in pregnancy:** There are insufficient data on the use of this combination or its individual components, Fluticasone Furoate, Umeclidinium, and Vilanterol, in pregnant women to inform a drug-associated risk. Triflo Arocap should be used during late gestation and labor only if the potential benefit justifies the potential for risks related to beta-agonists interfering with uterine contractility.

**Use in lactation:** There is no information available on the presence of Fluticasone Furoate, Umeclidinium or Vilanterol in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Triflo Arocap.

**Use in children:** This combination is not indicated for use in children and adolescents. The safety and efficacy in pediatric patients (aged 17 years and younger) have not been established.

**Use in hepatic impaired patients:** It has not been studied in subjects with hepatic impairment.

**Use in renal impaired patients:** It has not been studied in subjects with renal impairment.

## DRUG INTERACTIONS

**Strong cytochrome P450 3A4 inhibitors (e.g., ketoconazole):** May cause systemic corticosteroid and cardiovascular effects.

**Monoamine oxidase inhibitors and tricyclic antidepressants:** May potentiate the effect of vilanterol on the vascular system.

**Beta-blockers:** May block bronchodilator effects of beta-agonists and produce severe bronchospasm.

**Diuretics:** Electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with concomitant beta-agonists

**Anticholinergics:** Avoid administration with other anticholinergic-containing drugs.

## OVERDOSE

No human overdosage data has been found.

## STORAGE

Store below 30°C, Keep in a dry place & protect from light. Keep out of the reach of children.

## PACKING

**Triflo Arocap Capsule:** Each box contains 10's capsules in alu-alu blister pack.