

# Aroflo<sup>®</sup> Arocap

Salmeterol & Fluticasone Propionate  
Dry Powder Inhalation Capsule

## COMPOSITION

**Aroflo<sup>®</sup>-100** Arocap: Each inhalation capsule contains Salmeterol Xinafoate BP equivalent to Salmeterol 50 µg and Fluticasone Propionate BP 100 µg.

**Aroflo<sup>®</sup>-250** Arocap: Each inhalation capsule contains Salmeterol Xinafoate BP equivalent to Salmeterol 50 µg and Fluticasone Propionate BP 250 µg.

**Aroflo<sup>®</sup>-500** Arocap: Each inhalation capsule contains Salmeterol Xinafoate BP equivalent to Salmeterol 50 µg and Fluticasone Propionate BP 500 µg.

## PHARMACOLOGY

**Aroflo<sup>®</sup>** Arocap is a combination of Salmeterol and Fluticasone Propionate. Salmeterol is a selective, long acting  $\beta_2$ -agonist used in the treatment of asthma and other forms of diffuse airways obstruction. Fluticasone Propionate is a corticosteroid with potent anti-inflammatory activity. Fluticasone Propionate is stated to exert a topical effect on the lungs without systemic effects at usual dose.

## INDICATIONS

### Asthma-

**Aroflo<sup>®</sup>** Arocap is indicated in the regular treatment of asthma where use of a combination product (long-acting  $\beta_2$ -agonist and inhaled corticosteroid) is appropriate:

- Patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting  $\beta_2$ -agonist or
- Patients already adequately controlled on both inhaled corticosteroid and long-acting  $\beta_2$ -agonist.

### Chronic Obstructive Pulmonary Disease (COPD)-

**Aroflo<sup>®</sup>** Arocap is indicated for the symptomatic treatment of patients with COPD, with a FEV<sub>1</sub> <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.

## DOSAGE & ADMINISTRATION

Patients should be made aware that **Aroflo<sup>®</sup>** Arocap must be used daily for optimum benefit, even when asymptomatic.

### Asthma-

Adults and Adolescents (12 years and older)

**Aroflo<sup>®</sup>-100** Arocap: One capsule two times daily

**Aroflo<sup>®</sup>-250** Arocap: One capsule two times daily

**Aroflo<sup>®</sup>-500** Arocap: One capsule two times daily

### Children (4 years and older)

**Aroflo<sup>®</sup>-100** Arocap: One capsule two times daily

The maximum licensed dose of Fluticasone Propionate delivered by Aroflo AroHaler in children is 100 µg two times daily.

There are no data available for use of **Aroflo<sup>®</sup>** Arocap in children aged under 4 years.

### COPD-

Adults

**Aroflo<sup>®</sup>-500** Arocap: One capsule two times daily

**Using the AroHaler:** This is a patient friendly, ready to use and easy to grip device. Use as per instruction for use.

## CONTRAINDICATIONS

**Aroflo<sup>®</sup>** Arocap is contraindicated in patients with hypersensitivity to any of the active substances or to the excipients of this preparation.

## SIDE EFFECTS

As **Aroflo<sup>®</sup>** Arocap contains Salmeterol and Fluticasone Propionate, the type and severity of adverse reactions associated with each of the compounds may be expected. There is no incidence of additional adverse events following concurrent administration of the two compounds. The pharmacological side effects of  $\beta_2$ -agonist treatment, such as tremor, palpitations and headache have been reported, but tend to be transient and reduce with regular therapy. Cardiac arrhythmia may occur. There have been reports of arthralgia and hypersensitivity reactions, including rash, oedema and angioedema. There have been reports of oropharyngeal irritation.

Due to the Fluticasone Propionate component, hoarseness and candidiasis (thrush) of the mouth and throat can occur in some patients. Both hoarseness and incidence of candidiasis may be relieved by gargling with water after using the product. Symptomatic candidiasis can be treated with topical anti-fungal therapy whilst still continuing with the **Aroflo<sup>®</sup>** Arocap Dry Powder Inhalation Capsule. Possible systemic effects in children include adrenal suppression, growth retardation, decrease in bone mineral density.

## PRECAUTIONS

**Aroflo<sup>®</sup>** Arocap should not be used to treat acute asthma symptoms for which a fast and short acting bronchodilator is required. **Aroflo<sup>®</sup>** Arocap should not be stopped abruptly. It should be administered with caution in patients with pulmonary tuberculosis. **Aroflo<sup>®</sup>** Arocap should be used with caution in patients with severe cardiovascular disorders, heart rhythm abnormalities, diabetes mellitus, thyrotoxicosis, uncorrected hypokalemia or patients predisposed to low levels of serum potassium. Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur than with oral corticosteroids. It is important, therefore, that the patient is reviewed regularly and the dose of inhaled corticosteroid is reduced to the lowest dose at which effective control of asthma is maintained.

## USE IN SPECIAL GROUPS

### Use in pregnancy:

There are insufficient data on the use of Salmeterol & Fluticasone Propionate during pregnancy. Administration of drugs to pregnant women should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

### Use in lactation:

There are no data available for human breast milk. Administration of Salmeterol & Fluticasone Propionate to women who are breast-feeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child.

### Special patient groups:

There is no need to adjust the dose in elderly patients or in those with renal impairment. There are no data available for use of **Aroflo<sup>®</sup>** Arocap in patients with hepatic impairment.

## DRUG INTERACTIONS

Both non-selective and selective  $\beta$ -blockers should be avoided in patients with asthma, unless there are compelling reasons for their use. Care should be taken while co-administering of CYP3A4 inhibitors (i.e. Ketoconazole, Ritonavir) & Salmeterol-Fluticasone as there is an increased risk of systemic side effects of individual component.

## STORAGE

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

## PACKING

**Aroflo<sup>®</sup>-100** Arocap: Each box contains 30's capsules in alu-alu blister pack.

**Aroflo<sup>®</sup>-250** Arocap: Each box contains 30's capsules in alu-alu blister pack.

**Aroflo<sup>®</sup>-500** Arocap: Each box contains 30's capsules in alu-alu blister pack.

Manufactured by:  
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