

# Arotide®

Salmeterol Xinafoate BP and Fluticasone Propionate BP HFA Inhaler

## DESCRIPTION

**Arotide®** metered dose inhaler is a combination of Salmeterol Xinafoate BP and Fluticasone Propionate BP. Salmeterol Xinafoate 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 mainly glucocorticoid activity. Fluticasone Propionate is stated to exert a topical effect on the lungs without systematic effects at usual dose.

## INDICATIONS

For the regular treatment of asthma, where the use of a combination product is appropriate. This may include:

- Patients on effective maintenance doses of long-acting  $\beta$ -2 agonists and inhaled corticosteroids.
- Patients who are symptomatic on current inhaled corticosteroid therapy.
- Initiation of maintenance therapy in those patients with moderate persistent asthma not adequately controlled on 'as needed' reliever medication, and who have moderate/severe airway limitation and daily symptoms requiring reliever medication every day.

## DOSAGE AND ADMINISTRATION

Adults and adolescents 12 years and older -

Two puffs of 25  $\mu$ g Salmeterol and 125  $\mu$ g Fluticasone Propionate twice daily. or,

Two puffs of 25  $\mu$ g Salmeterol and 250  $\mu$ g Fluticasone Propionate twice daily.

## CONTRAINDICATIONS

Hypersensitivity to this drug.

## SIDE EFFECTS

- Headache
- Hoarseness/dysphonia
- Throat irritation
- Candidiasis of mouth and throat
- Muscle cramps
- Arthralgia

## PRECAUTION AND WARNING

The management of asthma should normally follow a stepwise program and patient response should be monitored clinically and by lung function tests. Treatment of asthma should be in accordance with current National asthma treatment guidelines. This Inhaler is not for relief of acute symptoms for which a fast- and short-acting inhaled bronchodilator (eg. Salbutamol) is required. Patients should be advised to have their relief medication available at all times. Increasing use of short-acting bronchodilators to relieve symptoms indicates deterioration of control and patients should be reviewed by a physician. Sudden and progressive deterioration in control of asthma is potentially life threatening and the patient should be reviewed by a physician. Consideration should be given to increasing corticosteroid therapy. Also, where the current dosage of this Inhaler has failed to give adequate control of asthma, the patient should be reviewed by a physician.

For patients with asthma or COPD, consideration should be given to additional corticosteroid therapies and administration of antibiotics if an exacerbation is associated with infection.

## USE IN PREGNANCY AND LACTATION

Administration during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus or child.

Fluticasone Propionate and Salmeterol concentrations in plasma after inhaled doses are very low and therefore concentrations in human breast milk are likely to be correspondingly low. There are no data available for human breast milk.

## PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children. This is pressurized container. Do not puncture, break or burn even when empty. For oral inhalation only. Shake well before each use .

## PACKAGING

**Arotide® 250** : Each canister contains 120 puffs, each puff delivers Salmeterol Xinafoate BP equivalent to Salmeterol 25 mcg and Fluticasone Propionate BP 250 mcg.

**Arotide® 125** : Each canister contains 120 puffs, each puff delivers Salmeterol Xinafoate BP equivalent to Salmeterol 25 mcg and Fluticasone Propionate BP 125 mcg.

**SK•F**

Manufactured by

**ESKAYEF PHARMACEUTICALS LTD.**

TONGI, GAZIPUR, BANGLADESH

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