



Salmate[®]

Salmeterol Xinafoate
Long Acting Bronchodilator Inhalant

COMPOSITION

Salmate[®] inhaler : Each puff delivers Salmeterol Xinafoate INN equivalent to 25 µg Salmeterol INN. Each Salmate[®] inhaler canister contains 5 mg of Salmeterol INN as Xinafoate.

INDICATION

Inhaled Salmate[®] exerts a significant bronchodilating effect within 10 to 20 minutes of single-dose administration with asthma and this effect lasts for up to 12 hours or more.

Salmate[®] has a beneficial effect on airway mucociliary clearance that will reduce the incidence of respiratory tract infections.

Salmate[®] produces a significant protective effect against Exercise Induced Asthma (EIA) for up to 9 to 12 hours in both adolescents and adults.

Salmate[®] improves the overnight PEF (Peak Expiratory Flow Rate) and controls the symptoms of the patients with nocturnal asthma. The use of Salmate[®] avoids exposure of children to theophylline or high-dose corticosteroid, with their attendant risks.

Addition of Salmate[®] to inhaled corticosteroid therapy is significantly more effective in terms of an improvement in lung function, symptom control and a reduction in the use of rescue bronchodilator therapy (use of short acting beta₂-agonist).

Addition of Salmate[®] to inhaled corticosteroid therapy also significantly reduces the use of inhaled corticosteroids.

DOSAGE AND ADMINISTRATION

For inhalation only.

Adults and children over 4 years: 50 µg twice daily (two puffs with one minute gap in between every puff).

Patients aged ≥ 12 years only: More severe cases- 100 µg twice daily. (Four inhalations with one minute gap between every inhalation).

Children below 4 years: Not recommended at present.

CONTRAINDICATION AND PRECAUTION

Hypersensitivity to Salmeterol Xinafoate.

Salmate[®] inhalation aerosol should not be used to treat acute symptoms. In this case prescribe a short-acting inhaled beta₂ agonist as well as warn

them that increasing inhaled beta₂ agonist use is a signal of deteriorating asthma.

Salmate® inhalation aerosol is not a substitute for inhaled or oral corticosteroids. Corticosteroids should not be stopped or reduced when Salmate inhalation aerosol is initiated.

Hypokalaemia: May occur and is potentially serious. It is potentiated by concurrent administration of xanthine derivatives, steroids, diuretics and hypoxia. Monitor serum potassium levels in these situations.

Thyrotoxicosis: Use with caution.

Pregnancy and lactation: Experience is limited. Balance risks against benefits.

Hepatic Impairment: Because Salmeterol is extensively metabolised by the liver, patients with hepatic impairment receiving the drug should be closely monitored.

Paradoxical bronchospasms: Salmeterol should be discontinued immediately.

SIDE EFFECT

Dose related tremor, subjective palpitations and headaches are usually mild and transient. Skin reactions, muscle cramps, non-specific chest pain, local irritation and arthralgia have been reported.

DRUG INTERACTION

As with all the other beta₂-agonists there may be interaction with beta-blocking agents at the receptor site when given concomitantly.

Monoamino Oxidase Inhibitors and Tricyclic Antidepressants : These agent should be used with caution because Salmeterol may be potentiated by these agents.

OVERDOSAGE

Overdosage with salmeterol may be expected to result in exaggeration of the pharmacologic adverse effects associated with beta-adrenoceptor agonists, including tachycardia and/or arrhythmia, tremor, headache, and muscle cramps.

In these cases, therapy with Salmate® (Salmeterol Xinafoate) inhalation aerosol and all beta-agonist drugs should be stopped, supportive therapy

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provided, and judicious use of a beta-adrenergic blocking agent should be considered, bearing in mind the possibility that such agents can produce bronchospasm. Cardiac monitoring is recommended in cases of overdosage.

STORAGE CONDITION

The inhaler should be stored below 30°C. Protect from direct sunlight and heat.

The canister should not be broken, punctured or burnt, even when apparently empty.

Keep away from eyes. Keep out of reach of children.

HOW SUPPLIED

Salmate[®] inhaler : Each canister contains salmeterol INN 5 mg (minimum 200 puffs). Each puff delivers Salmeterol INN 25 µg.

