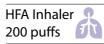
Sultolin® HFA Inhaler 200 puffs Salbutamol 100 mg/puff



COMPOSITION

Sultolin[®]: Each single actuation provides: 100 micrograms of Salbutamol from the actuator

INDICATION

Salbutamol HFA Inhaler is indicated for the treatment or prevention of bronchospasm in adults and children 4 years of age and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

DOSAGE & ADMINISTRATION

For treatment of acute episodes of bronchospasm or prevention of asthmatic symptoms, the usual dosage for adults and children 4 years of age and older is 2 inhalations repeated every 4 to 6 hours; in some patients, 1 inhalation every 4 hours may be sufficient. More frequent administration or a larger number of inhalations is not recommended. Exercise-Induced Bronchospasm Prevention: The usual dosage for adults and children 4 years and older is 2 inhalations 15 to 30 minutes hefore exercise

SIDE EFFECTS

In addition, Salbutamol, like other sympathomimetic agents, can cause adverse reactions such as hypertension, angina, vertigo, central nervous system stimulation, sleeplessness, headache, and drying or irritation of the oropharynx.

Tremor, nervousness, and headache appeared to be dose related.

Rare cases of urticaria, angioedema, rash, bronchospasm, and oropharyngeal edema have been reported after the use of inhaled Salbutamol. In addition, Salbutamol, like other sym-pathomimetic agents, can cause adverse reactions such as hypertension, angina, vertigo, central nervous system stimulation, insomnia, headache, and drying or irritation of the oropharynx.

PRECAUTION

Salbutamol as with all sympathomimetic amines should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, hypertension, and cardiac arrhythmia; in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines. Clinically significant changes in systolic and diastolic blood pressure have been seen in individual patients and could be expected to occur in some patients after use of any beta-adrenergic bronchodilator.

CONTRAINDICATION

Salbutamol is contraindicated in patients with a history of hypersensitivity to Salbutamol or any other components of Salbutamol.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. Plasma levels of Salbutamol Sulphate and HFA-134a after inhaled therapeutic doses are very low in humans, but it is not known whether the components of Salbutamol HFA excreted in human milk.

STORAGE

The Inhaler should be stored below 30°C, protected from direct sunlight and heat. The canister should not be broken, punctured or burnt, even when apparently empty. Keep away from eves. Keep out of reach of children.

HOW SUPPLIED

Sultolin[®]: Each Inhaler delivers 200 puffs.

Manufactured by

