

Ventolin™

Oral Preparation

Salbutamol

CP437/04

PRESENTATION :

VENTOLIN Tablets 2 mg each contain 2 mg salbutamol, as sulphate.

VENTOLIN Syrup contains 2 mg salbutamol as sulphate in each 5 ml of syrup.

Indications

VENTOLIN is a selective β_2 adrenoceptor agonist. At therapeutic doses it acts on the β_2 adrenoceptors of bronchial muscle, with little or no action on the β_1 adrenoceptors of the heart. It is suitable for the management and prevention of attack in asthma.

Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment as death may occur.

Patients with severe asthma have constant symptoms and frequent exacerbations, with limited physical capacity, and PEF values below 60% predicted at baseline with greater than 30% variability, usually not returning entirely to normal after a bronchodilator. These patients will require high dose inhaled (e.g. >1 mg/day beclomethasone dipropionate) or oral corticosteroid therapy. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision.

Relief of bronchospasm in bronchial asthma of all types, chronic bronchitis and emphysema. The management of uncomplicated premature labour during the third trimester of pregnancy following the control of uterine contractions with parenteral **VENTOLIN**.

Dosage and Administration

VENTOLIN has a duration of action of 4 to 6 hours in most patients.

Increasing use of β_2 agonists may be a sign of worsening asthma. Under these conditions a reassessment of the patient's therapy plan may be required and concomitant glucocorticosteroid therapy should be considered.

As there may be adverse effects associated with excessive dosing, the dosage or frequency of administration should only be increased on medical advice.

• Adults

The usual effective dose is 4 milligrams three or four times per day.

If adequate bronchodilation is not obtained each single dose may be gradually increased to as much as 8 milligrams.

Some patients obtain adequate relief with 2 milligrams three or four times daily.

In the management of premature labour, after uterine contractions have been controlled by intravenous infusion of **VENTOLIN** and the infusion has been withdrawn, maintenance therapy can be continued with oral **VENTOLIN**. The usual dosage is 4 milligrams, three or four times daily.

• Children

2 - 6 years - 1 to 2 milligrams ($1/2$ - 1 tablet of 2 milligrams) three or four times daily or 2.5-5 ml of syrup (1-2 mg salbutamol)

6 - 12 years - 2 mg (1 tablet of 2 milligrams) three or four times daily. (5 ml syrup)

Over 12 year - 2 - 4 milligrams (1 tablet of 2 milligrams) three or four times daily.

• Special patient groups

In elderly patients or in those known to be unusually sensitive to β -adrenergic stimulant drugs, it is advisable to initiate treatment with 2 milligrams salbutamol three or four times per day.

Contraindications

VENTOLIN Tablets are contraindicated in patients with a history of hypersensitivity to any of their components.

Although intravenous **VENTOLIN** and occasionally **VENTOLIN** tablets are used in the management of premature labour uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxæmia of pregnancy, **VENTOLIN** presentations should not be used for threatened abortion.

Warnings and Precautions

The management of asthma should normally follow a stepwise programme, and patient response should be monitored clinically and by lung function tests.

Increasing use of short-acting inhaled β_2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.

Patients should be warned that if either the usual relief is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

VENTOLIN should be administered cautiously to patients with thyrotoxicosis.

Potentially serious hypokalaemia may result from β_2 agonist therapy mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

In common with other β -adrenoceptor agonists, **VENTOLIN** can induce reversible metabolic changes, for example increased blood sugar levels. The diabetic patient may be unable to compensate for this and the development of ketacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

As maternal pulmonary oedema and myocardial ischaemia have been reported during or following treatment of premature labour with β_2 agonists, careful attention should be