Alvolex®

Salbutamol

Composition
Each 5 ml contains 2 mg Salbutamol (as Salbutamol Sulphate BP).

Therapeutic indications
Salbutamol is a selective beta-2 adrenoceptor agonist providing short-acting (4-6 hour) bronchodilatation in reversible airways obstruction. Salbutamol syrup can be used in the management of asthma, bronchospasm and/or reversible airways obstruction.
Relief of bronchospasm in bronchial asthma of all types.
Salbutamol syrup is suitable oral therapy for children and adults who are unable to use an inhaler device.

Dosages
Adults: The minimum starting dose is 2mg three times a day given as 5ml syrup. The usual effective dose is 4mg (10ml syrup) three or four times a day, which may be increased to a maximum of 8mg (20ml syrup) three or four times a day if adequate bronchodilatation is not obtained.
Elderly: In elderly patients or in those known to be unusually sensitive to beta-adrenergic stimulant drugs, it is advisable to initiate treatment with the minimum starting dose.
Children: 2 - 6 years: the minimum starting dose is 1mg as 2.5ml of syrup three times daily. This may be increased to 2mg as 5ml of syrup three or four times daily.
6-12 years: the minimum starting dose is 2mg as 5ml syrup three times daily. This may be increased to four times daily.
Over 12 years: the minimum starting dose is 2mg three times daily given as 5ml syrup. This may be increased to 4mg as 10ml syrup three or four times daily.
Salbutamol is well tolerated by children so that, if necessary, these doses may be cautiously increased to the maximum dose.
For lower doses the syrup may be diluted with freshly prepared purified water BP.

Contraindications
Although intravenous salbutamol and occasionally salbutamol tablets are used in the management of premature labour, uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage, or toxaemia of pregnancy, salbutamol presentations should not be used for threatened abortion.
Salbutamol oral preparations are contra-indicated in patients with a history of hypersensitivity to any of their components.

Special warnings and precautions
Bronchodilators should not be the only or main treatment in patients with severe or unstable asthma. Severe asthma requires regular medical assessment including lung function testing as patients are at risk of severe attacks and even death. Physicians should consider using oral corticosteroid therapy and/or the maximum recommended dose of inhaled corticosteroid in those patients.
Patients should seek medical advice if treatment with Salbutamol syrup becomes less effective. The dosage or frequency of administration should only be increased on medical advice.
Patients taking Salbutamol syrup may also be receiving short-acting inhaled bronchodilators to relieve symptoms.
Increasing use of bronchodilators in particular short-acting inhaled beta2-agonists to relieve symptoms indicates deterioration of asthma control. The patient should be instructed to seek medical advice if short-acting relief bronchodilator treatment becomes less effective or they need more inhalations than usual.
In this situation patients should be reassessed and consideration given to the need for increased anti-inflammatory therapy (eg. Higher doses of inhaled corticosteroids or a course of oral corticosteroid). Severe exacerbations of asthma must be treated in the normal way.
Patients should be warned that if either the usual relief with Salbutamol oral preparations 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.
Salbutamol syrup and non-selective beta-blocking drugs, such as propranolol, should not usually be prescribed together.
Salbutamol should be administered cautiously to patients suffering from thyrotoxicosis.
Potentially serious hypokalaemia may result from beta-2 agonist therapy mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids. It is recommended that serum potassium levels are monitored is such situations.
In common with other beta-adrenoceptor agonists, salbutamol can induce reversible metabolic changes such as increased blood glucose levels. Diabetic patients may be unable to compensate for the increase in blood glucose and the development of ketoacidosis has been reported.
Concurrent administration of corticosteroids can exaggerate this effect.

Drug interaction
None known.

Pregnancy and lactation
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.
As with the majority of drugs, there is little published evidence of its safety in the early stages of human pregnancy, but in animal studies there was evidence of some harmful effects on the foetus at very high dose levels.
As salbutamol is probably secreted in breast milk its use in nursing mothers requires careful consideration. It is not known whether salbutamol has a harmful effect on the neonate, and so its use should be restricted to situations where it is felt that the expected benefit to the mother is likely to outweigh any potential risk to the neonate.

Side-effects
Salbutamol syrup may cause fine tremor of skeletal muscle which occurs in some patients, usually the hands are most obviously affected. This effect is dose-related and is common to all beta-adrenergic stimulants. A few patients feel tense; this is also due to the effects on skeletal muscle and not to direct CNS stimulation. Tachycardia, with or without peripheral vasodilatation may rarely occur. In common with other beta-2 agonists, cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles) have been reported in association with the use of salbutamol, usually in susceptible patients.
Headaches have occasionally been reported.
There have been very rare reports of muscle cramps.
Hypersensitivity reactions including angioedema, urticaria, bronchspasm, hypotension and collapse have been reported very rarely.
Potentially serious hypokalaemia may result from beta-2 agonist therapy.
As with other beta-2 agonists hyperactivity in children has been reported rarely.

Commercial pack
Bottle containing 100 ml syrup.

Manufactured by :
Silva
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