Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Teva UK Limited on 0207 540 7117 or medinfo@tevauk.com

Please refer to the Summary of Product Characteristics (SmPC) for full details of Prescribing Information.

Salamol® (Salbutamol) Aerosol and Easi-Breathe® CFC-Free Inhalers Abbreviated Prescribing Information: P**resentation:** Salamol 100mcg Aerosol Inhaler. Salamol 100mcg Easi-Breathe Inhaler. One metered dose contains salbutamol sulfate equivalent to 100mcg salbutamol. **Indications:** Symptomatic treatment of asthma and other conditions with associated reversible airways obstruction. Use on an as required basis for relief of wheezing, shortness of breath. Prevention of asthma attacks induced by exercise or exposure to allergens. Can be used as relief medication to manage mild, moderate and severe asthma, provided its use does not delay the introduction and regular use of corticosteroid therapy where necessary. Indicated in adults, adolescents and children aged 4 to 11 years. **Dosage and Administration:** For optimum results in most patients use as required. Salamol 100mcg Aerosol inhaler can be used with a Volumatic® spacer. *Adults and Elderly:* For relief of acute asthma: One to two inhalations (100 to 200mcg). For prevention of exercise or allergen-induced asthma: Two inhalations (200mcg) 10 to 15 minutes before challenge. Do not exceed eight inhalations in 24 hours. Inhalations should not usually be repeated more often than every 4 hours. *Paediatric Population:* Relief of acute bronchospasm: Children under the age of 12 years: One inhalation (100mcg). The dose may be increased to two inhalations if required. Prevention of allergen or exercise-induced bronchospasm: Children under 12: one inhalation (100mcg) before challenge or exertion. The dose may be increased to two inhalations if required. Chronic therapy: Children under the age of 12 years: Up to two inhalations 4 times daily. Children aged 12 years and over: Dose as *per* adult population. **Contraindications:** Hypersensitivity to any of the components. Salbutamol inhalation is contraindicated in treatment of threatened abortion or premature labour. **Precautions and warnings:** Instruct patients in the proper use of their inhaler and check their technique. Asthma management should normally follow a stepwise programme. Monitor the patient's response clinically and by lung function tests. Patients who are prescribed regular anti-inflammatory therapy (e.g., inhaled corticosteroids) should be advised to continue taking their anti-inflammatory medication even when symptoms decrease. Asthmatic patients whose conditions deteriorates despite Salbutamol therapy, or where a previously effective dose fails to give relief for at least three hours, should seek medical advice as soon as possible in order that any necessary additional steps may be taken. Administer with caution to patients with thyrotoxicosis, coronary insufficiency, hypertrophic obstructive cardiomyopathy, arterial hypertension, known tachyarrhythmias, concomitant use of cardiac glycosides, diabetes mellitus and in patients with a history of bronchospasm. If bronchospasm occurs the preparation should be discontinued immediately, and an alternative therapy given. Solutions which are not of neutral pH may rarely cause paradoxical bronchospasm in some patients. Take care when treating acute asthma attacks or exacerbation of severe asthma, as increased serum lactate levels and rarely lactic acidosis have been reported after the use of high doses in emergency situations. This is reversible on reducing the dose. Salbutamol can induce reversible metabolic changes. Overuse of short-acting beta-agonists may mask the progression of the underlying disease and contribute to deteriorating asthma control, leading to an increased risk of severe asthma exacerbations and mortality. Patients who take more than twice a week "as needed" salbutamol, not counting prophylactic use prior to exercise, should be re-evaluated for proper treatment adjustment as these patients are at risk for overuse of salbutamol. Diabetic patients may be unable to compensate for the increase in blood glucose and may develop ketoacidosis. Concomitant administration of glucocorticoids can exaggerate this effect. Hypokalaemia may also occur. Monitor serum potassium levels. Not to be used for managing premature labour or for threatened premature labour or for threatened abortion. Contains ethanol (alcohol). **Interactions:** Propranolol and other non-cardioselective β-adrenoceptor blocking agents antagonise the effects of salbutamol. Increased risk of cardiovascular effects with monoamine oxidase inhibitors, tricyclic antidepressants and digoxin. Wherever possible, discontinue use at least six hours before anaesthesia with halogenic anaesthetics. Hypokalaemia occurring with β2-agonist therapy may be exacerbated by treatment with xanthines, steroids, diuretics and long-term laxatives. Because of the content of ethanol, there is theoretical potential for interaction in patients taking disulfiram or Metronidazole. **Pregnancy and Lactation:** The therapeutic benefits should be weighed against the potential risks to the foetus. Salbutamol inhalation is contraindicated in treatment of threatened abortion or premature labour. **Effects on ability to drive and use machines**: No studies on the effects on the ability to drive and use machines have been performed. **Adverse Reactions:** *Common:* Dose related tenseness and headaches, tachycardia, respiratory irritations (mouth and throat). *Serious:* Hypersensitivity reactions, potentially serious hypokalaemia, sleep disturbances and hallucinations (especially in children), hyperactivity in children (rarely), dizziness, tachycardia with or without peripheral vasodilatation (rarely), cardiac arrhythmias, palpitations, peripheral vasodilatation, Supraventricular tachycardia and extrasystoles, especially if used concomitantly with other ß2-agonists. Paradoxical

bronchospasm, nausea, vomiting, pruritus, fine tremor of skeletal muscle and myalgia. Consult the Summary of Product Characteristics in relation to other side effects. **Overdose:** An overdose may result in skeletal muscle tremor, tachycardia, tenseness, headache and peripheral vasodilatation. The preferred antidote for overdosage with salbutamol is a cardioselective ß-adrenoceptor blocking agent. Beta-blocking drugs should be used with caution in patients with a history of bronchospasm, as these drugs are potentially life threatening. Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored. Hyperglycaemia and agitation have also been reported following overdose with salbutamol. **Price:** *Per* 200 dose unit: Salamol 100mcg Aerosol Inhaler: £1.46, Salamol 100mcg Easi-Breathe Inhaler: £6.30. **Legal Category:** POM. **Marketing Authorisation Number:** Salamol 100 mcg Aerosol Inhaler PL 00530/0555; Salamol 100mcg Easi-Breathe Inhaler PL 00530/0556. **Marketing Authorisation Holder**: Norton Healthcare Limited, T/A IVAX Pharmaceuticals UK, Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX **Job Code:** MED-GB-00292. **Date of revision:** February 2024