Soltel

(Salmeterol 25 micrograms)

CFC-FREE INHALER

Abbreviated Prescribing Information

NAME OF MEDICINAL PRODUCT: Soltel CFC-free Inhaler 25 micrograms per actuation pressurised inhalation, suspension.
Each metered dose (ex-valve) contains 25 micrograms salmeterol (as xinafoate). This is equivalent to a delivered dose (ex-actuator) of 21 micrograms salmeterol (as xinafoate). Excipient(s):For a full list of excipients, see section 6.1. **THERAPEUTIC INDICATIONS:** Regular symptomatic add-on treatment of reversible airways obstruction in patients with asthma, including those with nocturnal asthma, who are inadequately controlled on inhaled corticosteroids in accordance with current treatment guidelines. Treatment of chronic obstructive pulmonary disease (COPD). Prevention of exercise-induced asthma. **POSOLOGY AND ADMINISTRATION:** For inhalation use. Soltel CFC-free Inhaler 25 micrograms should be used regularly. The full benefits of treatment will be apparent after several doses of the medicinal product. As there may be adverse reactions associated with excessive dosing with this class of medicinal product, the dosage or frequency of administration should only be increased on medical advice. Recommended Doses: **Asthma** *Adults and Adolescents over 12 years of age:* Two actuations of 25 micrograms salmeterol twice daily. In asthma patients with more severe airways obstruction up to four inhalations of 25 micrograms of salmeterol twice daily may be of benefit. *Children:* **The safety and efficacy of Soltel CFC-free Inhaler 25 micrograms have not been demonstrated in children. Therefore Soltel CFC-free Inhaler 25 micrograms should not be used in children 12 years of age and younger COPD** *Adults*: Two actuations of 25 micrograms salmeterol twice daily. *Children*: There is no relevant indication for use of Soltel CFC-free Inhaler 25 micrograms in children. *Special patient groups*: There is no need to adjust the dose in elderly patients or in those with renal impairment. There are no data available on the use of salmeterol in patients with hepatic impairment. **INSTRUCTIONS FOR USE**: Refer to section 4.2 of SPC. **Cleaning the inhaler:** Refer to section 4.2 of SPC. PATIENTS MUST NOT PUT METAL CANNISTER INTO WATER. **CONTRAINDICATIONS:** Soltel CFC-free Inhaler 25 micrograms is contraindicated in patients with hypersensitivity to salmeterol xinafoate or to any of the excipients (See Section 6.1). Soltel CFC-free Inhaler 25 micrograms contains soya lecithin and is contraindicated in patients who have peanut or soya allergies. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** The management of asthma should normally follow a stepwise programme and patient response should be monitored clinically and by lung function tests. Salmeterol should not be used (and is not sufficient) as the first treatment for asthma. Salmeterol is not a replacement for oral or inhaled corticosteroids. Its use is complementary to them. Patients must be warned not to stop steroid therapy and not to reduce it without medical advice even if they feel better on salmeterol. Salmeterol should not be used to treat acute asthma symptoms for which a fast and short-acting inhaled bronchodilator is required. Patients should be advised to have their medicinal product to be used for the relief of acute asthma symptoms available at all times. Increasing use of short-acting bronchodilators to relieve asthma 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 more inhalations than usual are required. In this situation the patient should be assessed and consideration given to the need for increased anti-inflammatory therapy (e.g. higher doses of inhaled corticosteroid or a course of oral corticosteroid). Severe exacerbations of asthma must be treated in the normal way. Although salmeterol may be introduced as add-on therapy when inhaled corticosteroids do not provide adequate control of asthma symptoms, patients should not be initiated on salmeterol during an acute severe asthma exacerbation, or if they have significantly worsening or acutely deteriorating asthma. Serious asthma-related adverse events and exacerbations may occur during treatment with salmeterol. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation on salmeterol. Sudden and progressive deterioration in control of asthma is potentially life-threatening and the patient should undergo urgent medical assessment. Consideration should be given to increasing corticosteroid therapy. Under these circumstances daily peak flow monitoring may be advisable. For maintenance treatment of asthma salmeterol should be given in combination with inhaled or oral corticosteroids. Long-acting bronchodilators should not be the only or the main treatment in maintenance asthma therapy (see Section 4.1). Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose of salmeterol. Regular review of patients as treatment is stepped down is important. The lowest effective dose of salmeterol should be used.As with other inhalational therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing and fall in expiratory flow rate (PEFR) after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. Salmeterol therapy should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted. Salmeterol should be administered with caution in patients with thyrotoxicosis.There have been very rare reports of increases in blood glucose levels (see section 4.8) and this should be considered when prescribing to patients with a history of diabetes mellitus. Cardiovascular effects such as increases in systolic blood pressure and heart rate may occasionally be seen with all sympathomimetic drugs, especially at higher than therapeutic doses. For this reason, salmeterol should be used with caution in patients with pre-existing cardiovascular disease. Potentially serious hypokalaemia may result from β2 agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by hypoxia and by concomitant treatment with xanthine derivatives, steroids and diuretics. Serum potassium levels should be monitored in such situations. **INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:** Beta adrenergic blockers may weaken or antagonise the effect of salmeterol. Both non-selective and selective β blockers should be avoided in patients with asthma unless there are compelling reasons for their use. Potentially serious hypokalaemia may result from β2 agonist therapy. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics. Potent CYP3A4 inhibitors: Co-administration of ketoconazole (400 mg orally once daily) and salmeterol (50 µg inhaled twice daily) in 15 healthy subjects for 7 days resulted in a significant increase in plasma salmeterol exposure (1.4-fold Cmax and 15-fold AUC). This may lead to an increase in the incidence of other systemic effects of salmeterol treatment (e.g. prolongation of QTc interval and palpitations) compared with salmeterol or ketoconazole treatment alone (see Section 4.4). Clinically significant effects were not seen on blood pressure, heart rate, blood glucose and blood potassium levels. Co-administration with ketoconazole did not increase the elimination half-life of salmeterol or increase salmeterol accumulation with repeat dosing.The concomitant administration of ketoconazole should be avoided, unless the benefits outweigh the potentially increased risk of systemic side effects of salmeterol treatment. There is likely to be a similar risk of interaction with other potent CYP3A4 inhibitors (e.g. itraconazole, telithromycin, ritonavir). Moderate CYP 3A4 inhibitors: Co-administration of erythromycin (500mg orally three times a day) and salmeterol (50 µg inhaled twice daily) in 15 healthy subjects for 6 days resulted in a small but non-statistically significant increase in salmeterol exposure (1.4 fold Cmax and 1.2- fold AUC). Co-administration with erythromycin was not associated with any serious adverse effects. **FERTILITY, PREGNANCY AND LACTATION:** There are limited data (less than 300 pregnancy outcomes) from the use of salmeterol in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity with the exception of evidence of some harmful effects on the fetus at very high dose levels (see section 5.3). As a precautionary measure, it is preferable to avoid the use of salmeterol during pregnancy. Available pharmacodynamic/toxicological data in animals have shown excretion of salmeterol in milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from salmeterol therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. Studies of HFA 134a revealed no effects on the reproductive performance and lactation of adult or two successive generations of rats or on the fetal development of rats or rabbits. **EFECTS ON ABILITY TO DRIVE AND USE MACHINERY:** Based on the pharmacodynamic profile of salmeterol and reported adverse effects there is no or negligible influence of salmeterol on the ability to drive and use machines. **UNDESIRABLE EFFECTS:** Adverse effects are listed below by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 and < 1/10), uncommon (≥ 1/1000 and < 1/100), rare (≥ 1/10,000 and < 1/1000) and very rare (< 1/10,000) including isolated reports. Common and uncommon events were generally determined from clinical trial data. The incidence on placebo was not taken into account. Very rare events are generally determined from post-marketing spontaneous data. The following frequencies are estimated at the standard dose of 50 µg twice daily. Frequencies at the higher dose of 100 µg twice daily have also been taken to account where appropriate. Immune system disorders: Hypersensitivity reactions: Uncommon: rash (itching and redness).Very rare: anaphylactic reactions including oedema and angioedema, bronchospasm and anaphylactic shock Metabolism and nutrition disorders: Rare: hypokalaemia. Very rare: hyperglycaemia. Psychiatric disorders: Uncommon: nervousness. Rare: insomnia Nervous system disorders: Common:tremor and headache Rare: dizziness. Cardiac disorders: Common: palpitations Uncommon: tachycardia. Very rare: cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles) Respiratory, thoracic and mediastinal disorders: Very rare: oropharyngeal irritation and paradoxical bronchospasm. Gastrointestinal disorders: Very rare: nausea.Musculoskeletal, connective tissue and bone disorders: Common: muscle cramps. Very rare: arthralgia General disorders and administration site conditions: Very rare: non-specific chest pain The pharmacological side effects of β2 agonist treatment, such as tremor, headache and palpitations have been reported, but tend to be transient and to reduce with regular therapy. Tremor and tachycardia occur more commonly when administered at doses higher than 50 µg twice daily. As with other inhalational therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing and fall in expiratory flow rate (PEFR) after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. Salmeterol therapy should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted (see section 4.4). **OVERDOSE:** The signs and symptoms of a salmeterol over dose are dizziness, increases in systolic blood pressure, tremor, headache and tachycardia. The preferred antidotes are cardio selective β blocking agents, which should be used with extreme caution in patients with a history of bronchospasm. Additionally, hypokalaemia can occur and therefore serum potassium levels should be monitored. Potassium replacement should be considered. **MARKETING AUTHORISATION HOLDER:** Cipla (EU) Limited, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW **MARKETING AUTHORISATION NUMBER:** PL 36390/0074 **Legal Category:** POM

Reporting of suspected adverse reactions
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 Kent Pharmaceuticals on 01233 506574 or medical@dccvital.com

For a copy of the SmPC or further medical information, please contact medical@DCCvital.com

Ref: UK 2017/2/SmPC July 2014

Date of revision: March 2017