Serevent Accuhaler (50mcg salmeterol) & Serevent Evohaler (25mcg salmeterol) Prescribing Information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing.

Name & Presentation: Serevent® Accuhaler® (50mcg salmeterol) inhalation powder and Serevent® Evohaler® (25mcg salmeterol) pressurised inhalation suspension. **Indication:** Salmeterol is a selective β2-agonist. **Accuhaler**: Indicated for reversible airways obstruction in patients with asthma and chronic obstructive pulmonary disease (COPD). In asthma (including nocturnal asthma and exercise induced symptoms) it is indicated for those treated with inhaled corticosteroids (ICS) who require a long-acting beta agonist in accordance with current treatment guidelines. Serevent Accuhaler is not a replacement for inhaled or oral corticosteroids which should be continued at the same dose, and not stopped or reduced, when treatment with Serevent Accuhaler is initiated. **Evohaler:** Asthma**:** Serevent is indicated for the regular symptomatic add-on treatment of reversible airways obstruction in patients with asthma, including those with nocturnal asthma, who are inadequately controlled on ICS in accordance with current treatment guidelines. Serevent is also indicated in the prevention of exercise-induced asthma. COPD: Serevent is indicated in the treatment of patients with COPD. **Dosage and administration:** Inhalation use only. Patients should be instructed in proper use of their inhaler and technique to optimise delivery. **Accuhaler** Asthma: Adults: 50 micrograms twice daily, increasing to 100 micrograms twice daily if required. Children 4 years and older: 50 micrograms twice daily. COPD: Adults: 50 micrograms, twice daily. Children: Not appropriate. **Evohaler** Asthma: Adults and adolescents 12 years and older: 50 micrograms twice daily. In patients with asthma with more severe airways obstruction up to 100 micrograms twice daily may be of benefit. Children 4 years and older: 50 micrograms twice daily. COPD: Adults 18 years and older: 50 micrograms twice daily. **Contra-indications:** Hypersensitivity to salmeterol xinafoate or any of the excipients. **Precautions:** Serevent should not be used (and is not sufficient) as the first treatment for asthma. Patients should not be initiated on Serevent 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 Serevent. Sudden and progressive deterioration in control of asthma is potentially life-threatening and the patient should undergo urgent medical assessment. Once asthma symptoms are controlled, Serevent dose may be reduced with regular review. Parodoxical broncospasm may occur with an immediate increase in wheezing and fall in peak expiratory flow rate after dosing. This should be treated immediately, Serevent should be discontinued and if necessary alternate therapy instituted. 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. Use with caution in patients with pre-existing CV disease. Administer with caution in patients with thyrotoxicosis. Administer with caution in patients with a diabetes due to potential for increase in blood glucose levels. 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. Data from a large asthma trial suggested patients of black African or Afro-Caribbean ancestry were at increased risk of serious respiratory-related events or deaths when using salmeterol. Patients should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen whilst using Serevent. **Interactions:** See SmPC for full details. Beta-adrenergic blockers may weaken or antagonise the effect of salmeterol. Both non-selective and selective β-blockers should be avoided unless there are compelling reasons for their use. Hypokalaemia caused by β2 agonist may be potentiated by xanthine derivatives, steroids, diuretics and hypoxia, so monitor potassium. Avoid concomitant use of ketoconazole or other potent CYP3A4 inhibitors unless the benefits outweigh the potentially increased risk of systemic side effects of salmeterol treatment (e.g. QTc interval prolongation). **Pregnancy and lactation:** As a precautionary measure, avoid the use of Serevent during pregnancy. Available pharmacodynamic/toxicological data in animals have shown excretion of salmeterol in milk. A risk to the suckling child cannot be excluded. Use in breast-feeding should consider the benefit of breast feeding for the child and the benefit of therapy for the woman. **Adverse Effects:** See SmPC for full list of adverse effects. Common (≥1/100 to <1/10): headache, tremor, palpitations and muscle cramps**.** Other serious: Uncommon (≥1/1000 to <1/100): tachycardia. Rare (≥1/10,000 to <1/1000) hypokalaemia. Very rare (<1/10,000) anaphylactic reactions, hyperglycaemia, cardiac arrhythmias, paradoxical bronchospasm, non-specific chest pain. Overdose: signs and symptoms of salmeterol overdosage are those typical of excessive β2-adrenergic stimulation. **Legal classification:** POM **Marketing authorisation (MA) number & cost:** Serevent Accuhaler: 60 doses £35.11 (PL 10949/0214). Serevent Evohaler: 120 doses £29.26 (PL 10949/0369). **MA Holder:** Glaxo Wellcome UK Ltd, 980 Great West Road, Brentford, TW8 9GS. Serevent is a registered trade mark of the GlaxoSmithKline Group of Companies. **Last revised:** April 2020 **CL reference:** PI-5517

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellowcard in the Google Play or Apple App Store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.