

November 2018

Prescribing Information

(Please refer to the full Summary of Product Characteristics (SPC) before prescribing)

Seretide Accuhaler and Evohaler (salmeterol xinafoate and fluticasone propionate)

Uses: Asthma: Regular treatment of asthma, where use of a combination product (LABA and ICS) is appropriate, i.e. patients not adequately controlled on ICS and 'as needed' short-acting inhaled bronchodilator or patients controlled on ICS and LABA. Note: Seretide 50 Evohaler and Seretide 100 Accuhaler are not appropriate in severe asthma. COPD: Symptomatic treatment of patients with COPD with a FEV1 <60% predicted normal (prebronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. **Dosage and administration: See SPC for more detail on dosing** Inhalation only. Asthma: *Adults and adolescents ≥12 years:* Seretide Accuhaler- one inhalation b.d. of Seretide 100, 250 or 500 Accuhaler or Seretide Evohaler – two inhalations b.d. of Seretide 50, 125 or 250 Evohaler *Children 4-11 years:* Seretide 50 Evohaler two inhalations b.d. Volumatic or AeroChamber Plus spacer device use recommended. Seretide 100 Accuhaler one inhalation b.d. Maximum licensed dose of fluticasone propionate delivered by Seretide inhaler in children is 100 microgram twice daily. Regularly review patients and reduce dose to lowest that maintains effective symptom control. Where the control of symptoms is maintained with the lowest strength of the combination, patients may be prescribed an inhaled corticosteroid alone stepped down. COPD: one inhalation b.d. of Seretide 500 Accuhaler. **Contraindications:** Hypersensitivity to active substances or excipient; Accuhaler contains lactose monohydrate). **Special warnings and Precautions:** Not for acute treatment of asthma attack, nor initiation in significantly or acutely deteriorating asthma. Advise patients to seek medical attention if symptoms deteriorate. Caution in patients with: Pulmonary infections e.g. TB, fungal, viral;

severe cardiovascular disorders, heart rhythm abnormalities, diabetes mellitus, thyrotoxicosis and hypokalaemia. May cause cardiac arrhythmias, paradoxical bronchospasm post-dose, hyperglycaemia, β_2 agonist effects and pneumonia. Risk factors for pneumonia include current smoking, older age, low BMI and severe COPD. Systemic effects of inhaled corticosteroids may occur, particularly at high doses for prolonged periods, but much less likely than with oral steroids. Eye symptoms may be due to underlying serious conditions - consider referral to ophthalmologist. Cessation of and dose changes to steroids, transfer from oral steroids and stressful situations require caution. Regularly monitor height of children receiving prolonged treatment with ICS. The dose of ICS should be reduced to the lowest dose at which effective control of asthma is maintained. **Drug interactions:** Avoid betablockers in asthma. Potentially serious hypokalaemia may result from β_2 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. Avoid concomitant administration with potent and moderate CYP3A4 inhibitors unless benefits outweigh potential risk. **Pregnancy and lactation:** Experience limited. Balance risks against benefits. **Side effects:** *Very Common:* headache, nasopharyngitis. *Common:* oropharyngeal candidiasis, pneumonia (in COPD), bronchitis, hypokalaemia, throat irritation, hoarseness/dysphonia, sinusitis, contusions, muscle cramps, traumatic fractures, arthralgia, myalgia. *Serious other - uncommon:* hyperglycaemia, cataract cardiac arrhythmias, angina pectoris. *Rare:* oesophageal candidiasis, angioedema, respiratory symptoms (bronchospasm), anaphylaxis, Cushing's syndrome, cushingoid features, adrenal suppression, growth retardation in children and adolescents, decreased bone mineral density, behavioural changes (predominantly in children), glaucoma, cardiac arrhythmias and paradoxical bronchospasm. *Not known:* depression or aggression (predominantly in children). *Paradoxical bronchospasm:* substitute alternative therapy.

Legal category: POM. **Presentation and Basic NHS cost:** Accuhaler 60 inhalations. *Seretide 100* - £18.00. *Seretide 250* - £35.00. *Seretide 500* - £32.74. Evohaler 120 inhalations. *Seretide 50* - £18.00. *Seretide 125* - £23.45. *Seretide 250* - £29.32. **Product Licence (PL) nos:** 10949/0314-0316, 10949/0337-0339. **PL holder:** Glaxo Wellcome UK Limited, trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, UB11 1BT. **Last revision:** November 2018.

Zinc code: UK/RESP/0333/14(5). Seretide, Accuhaler and Evohaler are registered trademarks of the GlaxoSmithKline Group of Companies. **For the UK, further information is available from Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone: 0800 221 441.**

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