Seretide (salmeterol xinafoate and fluticasone propionate) Prescribing Information

(Please consult the Summary of Product Characteristics (SPC) before prescribing)

Seretide is available as an Evohaler or Accuhaler.

Quantitative list of active ingredients:
Seretide Accuhaler: Each pre-dispensed dose contains 50 µg salmeterol xinafoate and 100, 250 or 500 µg fluticasone propionate.
Seretide Evohaler: Each metered dose contains 25 µg salmeterol xinafoate and 50, 125 or 250 µg fluticasone propionate.
Indications:
Asthma (Evohaler and Accuhaler): Regular treatment of asthma, where use of a combination product (LABA and ICS) is appropriate, i.e. patients not adequately controlled on both ICS and 'as needed' short-acting inhaled β_2 agonist or patients already controlled on both ICS and LABA. Note: Seretide 25/50 Evohaler and Seretide 50/100 Accuhaler are not appropriate in severe asthma.
COPD (Accuhaler only): Symptomatic treatment of patients with COPD with a FEV_1 <60% predicted normal (prebronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy.
Dosage and method of use: See SPC for more details.
Asthma: *Adults and adolescents ≥12 years*: one inhalation b.d. of Seretide Accuhaler 50/100, 50/250 or 50/500; or two inhalations b.d. of Seretide Evohaler 25/50, 25/125 or 25/250. *Children 4-11 years*: two inhalations b.d. of Seretide Evohaler 25/50 (Volumatic spacer device can be used); or one inhalation b.d. of Seretide Accuhaler 50/100. Maximum licensed dose of fluticasone propionate delivered by Seretide inhaler in children is 100 µg twice daily. Regularly review patients and reduce dose to lowest that maintains effective symptom control. Where control of symptoms is maintained with the lowest strength of the combination, patients may be prescribed an inhaled corticosteroid alone stepped down.
COPD: *Adults*: one inhalation b.d. of Seretide Accuhaler 50/500.
Contraindications: Hypersensitivity to active substances or excipients; Accuhaler contains lactose monohydrate, Evohaler contains norflurane.
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.
Adverse reactions: *Very Common (≥1/10) :* headache, nasopharyngitis (in COPD). *Common (≥1/100 to <1/10):* oropharangeal candidiasis, pneumonia (in COPD), bronchitis (in COPD), hypokalaemia (in COPD), throat irritation, hoarseness/ dysphonia, sinusitis (in COPD), contusions (in COPD), muscle cramps, traumatic fractures (in COPD), arthralgia, myalgia**.** *Serious other – uncommon (≥1/1000 to <1/100):* hyperglycaemia, cataract, angina pectoris**.** *Rare (≥1/10,000 to <1/1000):* oesophageal candidiasis, angioedema, respiratory symptoms (bronchospasm), anaphylaxis, Cushings 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. *Frequency not known:* depression or aggression (predominantly in children). *Paradoxical bronchospasm*: substitute alternative therapy. Consult the SPC in relation to other adverse reactions.
Legal classification: POM.
Presentation, Basic NHS cost (excluding VAT) and Marketing Authorisation (MA) numbers: Accuhaler 60 inhalations: *Seretide Accuhaler 50/100* - £17.46, PL10949/0314; *Seretide Accuhaler 50/250* - £33.95, PL10949/0315; *Seretide Accuhaler 50/500* - £32.74, PL10949/0316. Evohaler 120 inhalations: *Seretide Evohaler 25/50* - £17.46, PL 10949/0337. *Seretide Evohaler 25/125* - £23.45, PL 10949/0338. *Seretide Evohaler 25/250* - £29.32, PL 10949/0339.
MA holder: Glaxo Wellcome UK Limited, trading as GlaxoSmithKline UK, 980 Great West Road, Brentford, Middlesex TW8 9GS, UK.
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Adverse events should also be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ 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.