SERETIDE
salmeterol/fluticasone propionate

gsk

What is Seretide Evohaler (salmeterol/fluticasone propionate) and who can use it?[1]

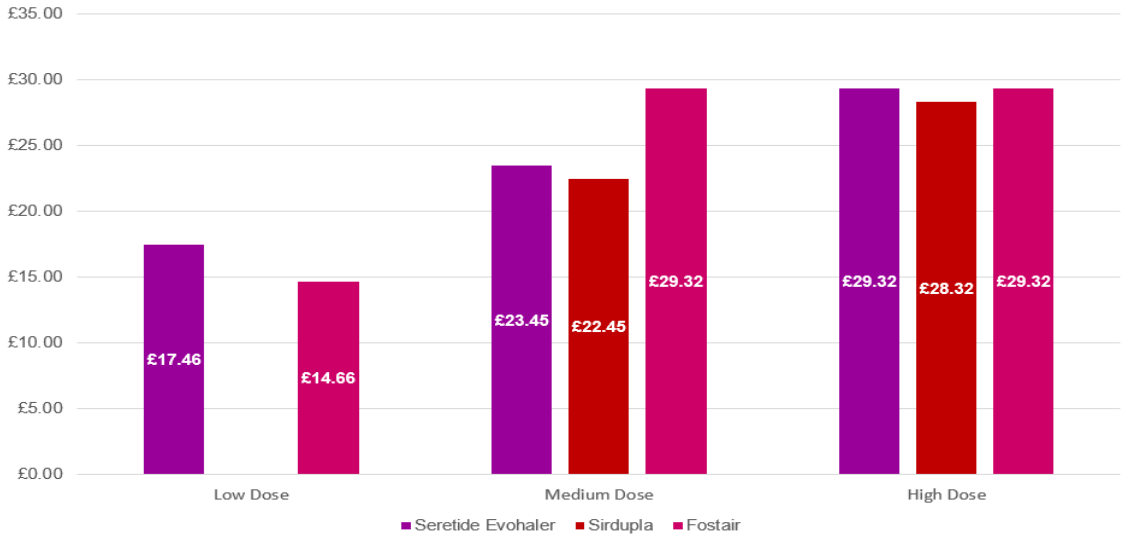
Seretide is indicated in the regular treatment of asthma where the use of a combination product (long-acting β2 agonist and inhaled corticosteroid) is appropriate: patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting β_2 agonist or patients already adequately controlled on both inhaled corticosteroid and long-acting β_2 agonist.

Seretide Evohaler is available in 3 doses:
Low dose 25/50 mcg b.d
Medium dose 25/125 mcg b.d
High dose 25/250 mcg b.d

- ✓ Licensed for paediatric asthma (ages 4-11 years)
- ✓ Licensed for use with a Volumatic spacer and Aerochamber
- ✓ Does not contain ethanol

Cost should no longer be a barrier to prescribing Seretide Evohaler

April 2020 cost comparison between Seretide Evohaler vs. Fostair (formoterol/beclomethasone) and Sirdupla (salmeterol/fluticasone propionate)[2,3]



Dose	Seretide Evohaler	Sirdupla	Fostair
Low	50/25 (2 puffs B.D)	n/a	100/6 (1 puff B.D)
Medium	125/25 (2 puffs B.D)	125/25 (2 puffs B.D)	100/6 (2 puffs B.D)
High	250/25 (2 puffs B.D)	250/25 (2 puffs B.D)	200/6 (2 puffs B.D)

Seretide Evohaler 25/125mcg costs £23.45 which is £5.87 less expensive than Fostair 100/6mcg b.d[2,4]

Seretide Evohaler provides guideline defined asthma control

- ✓ **In the GOAL study 75%** of patients given Seretide Evohaler achieved guideline defined control and were still well controlled after **1 year**[5]
- ✓ Patients should not need their rescue inhaler **6 days out of 7**[6]* (GOAL data extrapolated from 1 year to 1 week)

*GOAL Study Stratum 2 patients defined as those patients who were on 500 µg or less of beclomethasone propionate daily or equivalent

After over 100 million patient treatment years[7], the side effect profile of Seretide is very well established and includes: Very Common: Headache, nasopharyngitis Common: Oropharangeal candidiasis, pneumonia (in COPD), bronchitis, hypokalaemia, throat irritation, hoarseness/dysphonia, sinusitis, contusions, muscle cramps, traumatic fractures, arthralgia, myalgia. For a full list of side effects please see the SPC.

Prescribe Seretide Evohaler by brand to ensure your patients get Seretide

- **BTS/SIGN 2019 Asthma Guidelines** recommend inhaled medication is prescribed by brand[8]
- There is **no cost advantage** to the NHS prescribing salmeterol/fluticasone propionate as Seretide is the named proprietary product in the Drug Tariff[9]. This means all non-branded salmeterol/fluticasone propionate scripts are reimbursed at the Seretide list price, irrespective of what is dispensed.

References

1. Seretide SPC August 2019 (REF-27690)
2. eMIMS – https://www.mims.co.uk/drugs/respiratory-system/asthma-copd/Fostair (accessed April 2020) (REF-21884)
3. eMIMS – https://www.mims.co.uk/drugs/respiratory-system/asthma-copd/Sirdupla (accessed April 2020) (REF-25896)
4. Patient Data, IQVIA Solutions UK Ltd, March 2019 (REF-26242)
5. Bateman ED et al. Am J Respir Crit Care Med 2004; 170:836–844. (REF - 1902)
6. Woodcock et al Prim Care Respir J 2007 Page 159 Table 2. (DOF 2019N414203)
7. Data on File: Seretide Exposure in Asthma and COPD Sept 2018 (REF-11782)
8. BTS/SIGN. British Guideline on the Management of Asthma 2019 accessed July 2019
9. NHS Drug Tariff December 2019; page 221

Prescribing Information

April 2020

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, β2 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 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. 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: oropharangeal candidiasis, pneumonia (in COPD), bronchitis, hypokalaemia, throat irritation, hoarseness/ dysphonia, sinusitis, contusions, muscle cramps, traumatic fractures, arthralgia, myalgia. Serious other - uncommon: hyperglycaemia, cataract, angina pectoris. Rare: 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. 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 - £17.46. Seretide 250 - £33.95. Seretide 500 - £32.74. Evohaler 120 inhalations. Seretide 50 - £17.46. 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, 980 Great West Road, Brentford, Middlesex TW8 9GS Last revision: April 2020. Content Lab Code: PI-5348. Seretide, Accuhaler and Evohaler are registered trademarks of the GlaxoSmithKline Group of Companies.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MRHA Yellowcard in the Google Play or Apple App Store. Adverse events should also be reported to GlaxoSmithKline on 0800 221441.