Prescribing information for Stalpex (salmeterol xinafoate/ fluticasone propionate) 50 microgram/500 microgram/dose inhalation powder, pre-dispensed. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **Indications:** Asthma: Stalpex is indicated for use in patients with severe asthma 12 years of age and older only. Indicated in the regular treatment of patients with **severe** asthma where use of a combination product (long-acting ß2 agonist and inhaled corticosteroid) is appropriate: patients not adequately controlled on a lower strength corticosteroid combination product, or patients already adequately controlled on an inhaled corticosteroid in a high strength and a long-acting ß2 agonist. Chronic Obstructive Pulmonary Disease (COPD): Stalpex is indicated for the symptomatic treatment of patients with COPD, with a FEV_1 <60% predicted normal (pre-bronchodilator) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy. **Dosage and administration:** Use daily for optimum benefit, even when asymptomatic. **Titrate to the lowest dose at which effective control of symptoms is maintained.** Stalpex is only available in one strength therefore when titrating down, change to an alternative lower fixed-dose combination of salmeterol and fluticasone propionate. Asthma: Adults and adolescents 12 years and older: One 50 micrograms salmeterol and 500 micrograms fluticasone propionate inhalation twice daily. Once asthma is controlled, consider stepping down to a lower dose inhaled corticosteroid/ LABA combination or ICS alone. In general, inhaled corticosteroids remain the first line treatment. Stalpex is not intended for the initial management of mild or moderate asthma. Children: Limited data are available. COPD: Adults: One inhalation of 50 micrograms salmeterol and 500 micrograms fluticasone propionate twice daily. Elderly: no dose adjustment required. Renal impairment: no dose adjustment required. Hepatic impairment: no data are available for use of Stalpex in patients with hepatic impairment. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Precautions:** For severe asthma only; not for acute treatment, during an exacerbation or worsening asthma. Increased use of, or decreased response to, reliever medication indicates deterioration warranting physician review. Sudden and progressive deterioration is potentially life-threatening and the patient should undergo urgent medical assessment; consider increasing corticosteroid therapy. Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose of the inhaled corticosteroid and therefore a change to an alternative fixed-dose combination of salmeterol and fluticasone propionate containing a lower dose. The lowest dose of inhaled corticosteroid should be used. Treatment with Stalpex should not be stopped abruptly in patients with asthma due to risk of exacerbation. Therapy should be down-titrated under physician supervision. For patients with COPD, cessation of therapy may also be associated with symptomatic decompensation and should be supervised by a physician. Caution in patients with active or quiescent pulmonary tuberculosis and fungal, viral or other infections of the airway. Stalpex should be used with caution in patients with severe cardiovascular disorders or heart rhythm abnormalities and in patients with diabetes mellitus, thyrotoxicosis, uncorrected hypokalaemia or patients predisposed to low levels of serum potassium. Caution in diabetes mellitus (some reports of hyperglycaemia). If paradoxical bronchospasm develops, Stalpex should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary. Ensure regular review of patients on long term or high dose treatment to obtain lowest effective dose. Prolonged treatment of patients with high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crisis. Triggers of acute adrenal crisis include trauma, surgery, infection or any rapid reduction in dosage. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. Caution in patients transferring from oral steroids as they may remain at risk of impaired adrenal reserve for a considerable time. An increase in the incidence of pneumonia has been observed in patients with COPD receiving inhaled corticosteroids. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation. Adolescents <16 years taking high doses of fluticasone propionate (typically ≥ 1000 micrograms/ day) may be at particular risk. Systemic effects such as Cushing's syndrome, Cushingoid features, adrenal suppression, acute adrenal crisis and growth retardation in adolescents and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression may occur, particularly at high doses prescribed for long periods. Consider referring adolescents to a paediatric respiratory specialist. Regularly monitor the height of adolescents receiving prolonged treatment. Interaction with fluticasone: ß adrenergic blockers. Avoid non-selective and selective ß blockers. Potentially serious hypokalaemia may result from ß2 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 ritonavir (can greatly increase plasma concentration of fluticasone propionate). Combinations with CYP3A inhibitors should be avoided unless the benefit outweighs the potential increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects. Interaction with salmeterol: Avoid potent CYP3A4 inhibitors. **Adverse reactions:** Common and very common: Candidiasis of the mouth and throat, pneumonia (in COPD patients), bronchitis, hypokalaemia, headache, nasopharyngitis, throat irritation, hoarseness/dysphonia, sinusitis, contusions, muscle cramps, traumatic fractures, arthralgia, myalgia. Uncommon, rare and unknown frequency serious reactions: Oesophageal candidiasis, hypersensitivity reactions with the following manifestations; cutaneous hypersensitivity reactions, angioedema (mainly facial and oropharyngeal oedema), respiratory symptoms (dyspnoea), respiratory symptoms (bronchospasm), anaphylactic reactions including anaphylactic shock, Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in adolescents, decreased bone mineral density, hyperglycaemia, anxiety, sleep disorders, behavioural changes, including psychomotor hyperactivity and irritability (predominantly in adolescents), depression, aggression (predominantly in adolescents), tremor, cataract, glaucoma, blurred vision, palpitations, tachycardia, cardiac arrhythmias (including supraventricular tachycardia and extrasystoles), atrial fibrillation, angina pectoris, paradoxical bronchospasm. Please consult the summary of product characteristics for a full list of adverse reactions. **Marketing authorization number:** PL: 25258/0296. **Marketing Authorization Holder:** Glenmark Pharmaceuticals Europe Limited, Laxmi House, 2B Draycott Avenue, Kenton, Middlesex, HA3 0BU, United Kingdom **Distributor:** As above. **Legal classification:** POM. **Price:** £16.12. **Job code:** PP-UK-STAL-0047 **Date of preparation:** March 2022

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Glenmark Pharmaceuticals Europe Ltd medical_information@glenmarkpharma.com

Date of preparation: April 2022 PP-UK-STAL-0080

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