

Prescribing information for Stalplex (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: Stalplex 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 β_2 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 β_2 agonist. Chronic Obstructive Pulmonary Disease (COPD): Stalplex is indicated for the symptomatic treatment of patients with COPD, with a FEV₁ <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. Stalplex 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. Stalplex 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 Stalplex 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 Stalplex 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. Stalplex 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, Stalplex 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. Data from one trial suggested African-American patients were at increased risk of serious respiratory-related events or deaths when using salmeterol compared with placebo. Patients of black African or Afro-Caribbean ancestry should therefore be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen whilst using Stalplex. 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: β adrenergic blockers. Avoid non-selective and selective β blockers. 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 ritonavir (can greatly increase plasma concentration of fluticasone propionate). Caution with CYP3A inhibitors and avoid long-term treatment. Interaction with salmeterol: Avoid potent CYP3A4 inhibitors. **Pregnancy and lactation:** Animal studies have shown reproductive toxicity after administration of β_2 adrenoreceptor agonists and glucocorticosteroids; data on 300-1000 women indicate no malformative or fetoneonatal toxicity. It is unknown whether salmeterol and fluticasone propionate/metabolites are excreted in human milk and a risk to infants cannot be ruled out. **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:** £16.37. **Job code:** PP-UK-STAL-0037 **Date of preparation:** September 2020

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**