

## Sereflo® Metered Dose Inhaler (salmeterol xinafoate/fluticasone propionate)

### Prescribing Information

#### Please consult the full Summary of Product Characteristics (SmPC) before prescribing

Sereflo 25 microgram (µg) salmeterol xinafoate /125 µg or 250 µg fluticasone propionate per actuation pressurised inhalation, suspension. For both dose strengths the equivalent delivered dose per actuation is 21 µg of salmeterol and the delivered fluticasone propionate is 110 µg, for 125 µg dose strength and 220 µg, for 250 µg dose strength.

**INDICATIONS:** For use in adults with asthma 18 years of age and older only. Sereflo is indicated in the regular treatment of patients with moderate to severe asthma where use of a combination product (long-acting  $\beta_2$  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 mid or high strength and a long-acting  $\beta_2$  agonist.

**POSODOLOGY AND ADMINISTRATION: Patients should be instructed in the proper use of their inhaler (see SmPC and patient information leaflet).** Recommended doses in adults 18 years and older - Two inhalations of 25µg salmeterol and 125 µg or 250 µg fluticasone propionate twice daily. A short-term trial of salmeterol and fluticasone propionate may be considered as initial maintenance therapy in adults with moderate persistent asthma for whom rapid control of asthma is essential. In these cases, the recommended initial dose is two inhalations of 25 µg salmeterol and 50 µg fluticasone propionate twice daily.

**Note:** Sereflo is not available in a lower strength product containing salmeterol 25 µg and fluticasone propionate 50 µg. Therefore, when initiating therapy, or when it is appropriate to titrate down to a dose below 125 µg, an alternative fixed-dose combination of salmeterol and fluticasone propionate containing a lower dose of the inhaled corticosteroid is required. *Use of a spacer device;* where required in those with difficulties in

coordinating actuation of the inhaler with inspiration of breath, it is recommended ONLY for higher strength Sereflo containing salmeterol 25 µg and fluticasone propionate 250 µg. Patients should continue to use the same make of spacer device (Volumatic or the AeroChamber Plus) as switching between spacer devices can result in changes in the dose delivered to the lungs. **See the SmPC for further information on initiation, titration down and spacer use.**

**CONTRAINDICATIONS:** Hypersensitivity to either of the active substances or to any of the excipients.

**SPECIAL WARNINGS AND PRECAUTIONS:** Sereflo should not be used to treat acute asthma symptoms for which a fast- and short-acting bronchodilator is required. Patients should be advised to have their inhaler to be used for relief in an acute asthma attack available at all times. Patients should not be initiated on Sereflo during an exacerbation, or significantly worsening or acutely deteriorating asthma. Serious asthma-related adverse events and exacerbations may occur with Sereflo. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation. Treatment should not be stopped abruptly due to risk of exacerbation. Therapy should be down-titrated under physician supervision. All inhaled medication containing corticosteroids should be administered with caution in patients with active or quiescent pulmonary tuberculosis and fungal, viral or other infections of the airway. Salmeterol and fluticasone propionate 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 with a predisposition to low levels of serum potassium. Prescribers should also be aware of the risk of adrenal suppression and acute adrenal crisis which may occur in patients on prolonged treatment with high doses of inhaled corticosteroids. Systemic effects may occur with any inhaled corticosteroid and it is important therefore, that the patient is reviewed regularly and the dose of inhaled corticosteroid is reduced to the lowest dose at which effective control of asthma is maintained. Visual disturbances may be reported with steroid use. Patients

presenting with blurred vision or other visual disturbances should be considered for referral to an ophthalmologist.

**Drug Interactions:** Concomitant use should be avoided with; non-selective and selective  $\beta$  blockers, ritonavir and other potent/moderate CYP3A inhibitors, unless potential benefit outweighs the risk. Particular caution is advised in acute severe asthma as hypokalaemia may be potentiated by concomitant treatment with xanthine derivatives, steroids and diuretics.

**See the SmPC for further information on contraindications and precautions.**

**PREGNANCY AND LACTATION:** Balance risks against benefits.

**UNDESIRABLE EFFECTS:** Adverse events which have been associated with salmeterol/fluticasone propionate include: *Very common;* nasopharyngitis and headache; *Common;* candidiasis of the mouth and throat, pneumonia, bronchitis, hypokalaemia, throat irritation, hoarseness/dysphonia, sinusitis, contusions, muscle cramps, traumatic fractures, arthralgia and myalgia.

**For other adverse events please consult the full SmPC.**

**MARKETING AUTHORISATION HOLDER & PL NUMBERS:** Cipla (EU) Ltd, Dixcart House, Addlestone Road, Bourne Business Park, Addlestone, Surrey KT15 2LE. PL 36390/0237 and PL 36390/0238.

**Legal category:** POM. **NHS Cost** 25 µg/125 µg 1x 120 dose MDI £14.99 and 25 µg/250 µg 1x 120 doses MDI £19.99.

**Date of last revision:** September 2019.

**Adverse events should be reported.**  
Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for **MHRA Yellowcard** in the Google Play or Apple App Store. Adverse events should also be reported to Cipla (EU) Ltd on 0203 684 7710, [drugsafety@cipla.com](mailto:drugsafety@cipla.com)

### References

1. Sereflo 25 microgram/125 microgram. Summary of Product Characteristics.
2. Sereflo 25 microgram/250 microgram. Summary of Product Characteristics.
3. Malhotra G *et al.* *Eur Respir J.* 2014; **44(58)**: P940.
4. Garg M *et al.* *J Bioequiv Availab.* 2017; **9(6)**: 536-46.
5. MIMS.co.uk (accessed February 2020).