NEW

Breathe a little better

...with the new, cost effective brand alternative

Introducing

Sereflo™ **Metered Dose Inhaler**

(salmeterol / fluticasone)

Available in 25mcg/125mcg & 25mcg/250mcg doses

www.sereflo.ie

Fannin

Caring for Life since 1829

PART OF DCC VITAL

PHARMA DEVICES LOGISTICS

What is Sereflo™ indicated for?

Sereflo™ is indicated 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 β2 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 β2 agonist.

What do we know about asthma in Ireland*?

- Approximately 470,000 people have asthma in Ireland.
- Every 26 minutes, someone visits an Irish Hospital Emergency Department with asthma.
- One person dies every week in Ireland as a result of an asthma attack. 90% of asthma deaths are preventable.
- Irish adults miss on average 12 work days a year due to their asthma.
- The economic burden of Asthma costs the Irish state over €500 million per annum.
- 40% of Asthma Society of Ireland members surveyed say they do not take their asthma medication as prescribed due to cost.

What is the active ingredient in Sereflo™?

Each metered dose (ex valve) contains:

- 25 micrograms of salmeterol (as salmeterol xinafoate) and 125 or 250 micrograms of fluticasone propionate.
- This is equivalent to a delivered dose (ex actuator) of 21 micrograms of salmeterol and 110 or 220 micrograms of fluticasone propionate.

*Ref: Asthma Society of Ireland, www.asthma.ie, extracted May 2017.

Why switch to Sereflo™?

- **Sereflo™** is therapeutically equivalent to the market leader.
- **Sereflo™** is a more cost effective alternative to the market leader for your patient.
- **Sereflo™** is packaged in a tamper-evident sealed pouch for greater patient safety.
- **Sereflo™** has the unique front-facing dose counter which helps patient keep track of the amount of medicine left in the canister.

What are the advantages of an integrated dose counter for the patient?

- 95% patient satisfaction based on 'ease of use' and 'convenience'.
- 81% of patients are more satisfied with the device, as compared with MDIs without counters used in the past.
- Patients agreed that the dose counter would:
  - ✓ Assure them of medication supply: 92%
  - ✓ Help them avoid running out of medication: 92%
  - ✓ Allow them to monitor medication use: 91%
  - ✓ Help them take medication as directed: 77%
  - ✓ Help improve control of the disease: 73%
  - ✓ Help them know when to refill: 95%

*Patient satisfaction with an integrated dose counter on fluticasone / salmeterol pMDI, Int J Clin Pract. 2006; 60(10): 1218-1224).

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(salmeterol / fluticasone)
Available in 25mcg/125mcg & 25mcg/250mcg doses

NAME OF MEDICINAL PRODUCT:

Sereflo 25 microgram/125 or 250 microgram per actuation pressurised inhalation, suspension
(Please refer to the full Summary of Product Characteristics before prescribing)

The active is salmeterol (as **salmeterol xinafoate**) and **fluticasone propionate**. Excipient(s): For a full list of excipients, see section 6 of the SmPC. **THERAPEUTIC INDICATIONS: Sereflo is indicated 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 β2 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 β2 agonist.

POSOLOGY AND ADMINISTRATION: Sereflo is indicated in adults 18 years of age and older only. Sereflo is not indicated for use in children. **Posology:** Route of administration: **Inhalation use: Recommended Doses in Adults 18 years and older**

- Two inhalations of 25 micrograms salmeterol and 125 or 250micrograms 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 (defined as patients with daily symptoms, daily rescue use and moderate to severe airflow limitation) for whom rapid control of asthma is essential. In these cases, the recommended initial dose is two inhalations of 25 micrograms salmeterol and 50 micrograms fluticasone propionate twice daily. Note: Sereflo is only available in two strengths, it is not available in a lower strength product containing salmeterol 25 microgram and fluticasone propionate 50 microgram, a strength which is available for other similar fixed-dose combination products containing these two actives and currently available on the market. Therefore, when it is appropriate to titrate down to a dose of inhaled corticosteroid below 125 micrograms, a change to an alternative fixed-dose combination of salmeterol and fluticasone propionate containing a lower dose of the inhaled corticosteroid is required. This should be considered when prescribing further information is provided in the full SmPC. Without the lowest strength (25/50 microgram) of this fixed-dose combination, initiation of therapy in the majority of patients with asthma may be difficult and the lowest strength of the innovator product may be required. **Paediatric population:** The safety and efficacy of Sereflo in children have not been established. No data are available. **Spacer devices:** Use of a spacer device with Sereflo is recommended in patients who have, or are likely to have difficulties in coordinating actuation of the inhaler with inspiration of breath. **Use of a spacer device is recommended ONLY for Sereflo containing salmeterol 25 microgram and fluticasone propionate 250 microgram (the high strength inhaler).** A spacer device is not recommended for use with Sereflo containing salmeterol 25 microgram and fluticasone propionate 125 microgram (the mid/lower strength inhaler). If a spacer device is required for use with this mid/lower strength, the patient will have to change to an alternative fixed-dose combination of salmeterol and fluticasone propionate containing salmeterol 25 microgram and fluticasone propionate 125 microgram which is authorised for use with a spacer device. See the SmPC for further information on spacers. **Special patient groups:** There is no need to adjust the dose in elderly patients or in those with renal impairment. There are no data available for use of salmeterol and fluticasone propionate in patients with hepatic impairment. **Instructions for Use:** Patients should be instructed in the proper use of their inhaler (see patient information leaflet). The inhaler has been designed for use in a vertical position. **Testing, Use and cleaning of the inhaler:** See the SmPC section 4.2 for further information. **CONTRAINDICATIONS:** Hypersensitivity (allergy) to either of the active substances or to the excipient listed in Section 6.1. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** 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 if they have significantly worsening or acutely deteriorating asthma. Serious asthma-related adverse events and exacerbations may occur during treatment with Sereflo. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation on Sereflo. Details of management in worsening and improving control of this disease are provided in the full SmPC. The lowest effective dose of salmeterol and fluticasone propionate should be used (see section 4.2). **Treatment with Sereflo should not be stopped abruptly due to risk of exacerbation**. **Therapy should be down-titrated under physician supervision.** As with all inhaled medication containing corticosteroids, Sereflo should be administered with caution in patients with active or quiescent pulmonary tuberculosis and fungal, viral or other infections of the airway. Appropriate treatment should be promptly instituted, if indicated. Rarely, salmeterol and fluticasone propionate may cause cardiac arrhythmias e.g. supraventricular tachycardia, extrasystoles and atrial fibrillation, and a mild transient reduction in serum potassium at high therapeutic doses. 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 patients predisposed to low levels of serum potassium. There have been very rare reports of increases in blood glucose levels (see section 4.8) and this should be considered when prescribing to patients with a history of diabetes mellitus. As with other inhalation therapy paradoxical bronchospasm may occur with an immediate increase in wheezing and shortness of breath after dosing. Paradoxical bronchospasm responds to a rapid-acting bronchodilator and should be treated straightaway. **Sereflo should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary**. The pharmacological side effects of β_2 agonist treatment, such as tremor, palpitations and headache, have been reported, but tend to be transient and reduce with regular therapy. Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur than with oral

corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). **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.** Prolonged treatment of patients with high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crisis. Very rare cases of adrenal suppression and acute adrenal crisis have also been described with doses of fluticasone propionate between 500 and less than 1000 micrograms. Situations, which could potentially trigger acute adrenal crisis, include trauma, surgery, infection or any rapid reduction in dosage. Presenting symptoms are typically vague and may include anorexia, abdominal pain, weight loss, tiredness, headache, nausea, vomiting, hypotension, decreased level of consciousness, hypoglycaemia, and seizures. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. **Spacer devices:** Systemic absorption of salmeterol and fluticasone propionate is largely through the lungs. As the use of a spacer device with a metered dose inhaler may increase drug delivery to the lungs it should be noted that this could potentially lead to an increase in the risk of systemic adverse effects. The benefits of inhaled fluticasone propionate therapy should minimise the need for oral steroids, but patients transferring from oral steroids may remain at risk of impaired adrenal reserve for a considerable time. Therefore these patients should be treated with special care and adrenocortical function regularly monitored. **Steroids:** Patients who have required high dose emergency corticosteroid therapy in the past may also be at risk. This possibility of residual impairment should always be borne in mind in emergency and elective situations likely to produce stress, and appropriate corticosteroid treatment must be considered. The extent of the adrenal impairment may require specialist advice before elective procedures. **Ritonavir can greatly increase the concentration of fluticasone propionate in plasma. Therefore, concomitant use should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side-effects**. There is also an increased risk of systemic side effects when combining fluticasone propionate with other potent CYP3A inhibitors (see section 4.5 of SmPC). There was an increased reporting of lower respiratory tract infections (particularly pneumonia and bronchitis) in a 3 year study in patients with Chronic Obstructive Pulmonary Disease (COPD, please reference the SmPC for details of this study. **The safety and efficacy of Sereflo inhaler has not been established in patients with COPD and therefore Sereflo is not indicated for use in the treatment of patients with COPD.** 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 Sereflo. Concomitant use of systemic ketoconazole significantly increases systemic exposure to salmeterol. This may lead to an increase in the incidence of systemic effects (e.g. prolongation in the QTc interval and palpitations). Concomitant treatment with ketoconazole or other potent CYP3A4 inhibitors should therefore be avoided unless the benefits outweigh the potentially increased risk of systemic side effects of salmeterol treatment (see section 4.5 of SmPC). **Paediatric Population:** Sereflo is not indicated for paediatric populations. **The dose of inhaled corticosteroid should be reduced to the lowest dose at which effective control of asthma is maintained.** Sereflo is only available in two strengths; it is **not** available in a lower strength containing salmeterol 25 microgram and fluticasone propionate 50 microgram, the strength which would be prescribed for use in children. Furthermore, there are no data available on the use of Sereflo in children younger than 18 years of age. **FERTILITY, PREGNANCY AND LACTATION: Administration of salmeterol and fluticasone propionate to pregnant women should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus**. **Refer to SPC** . **EFECTS ON ABILITY TO DRIVE AND USE MACHINERY:** Sereflo has no or negligible influence on the ability to drive and use machines. **UNDESIRABLE EFFECTS:** As Sereflo contains salmeterol and fluticasone propionate, the type and severity of adverse reactions associated with each of the compounds may be expected. There is no incidence of additional adverse events following concurrent administration of the two compounds. Adverse events which have been associated with salmeterol/fluticasone propionate are given below, listed by system organ class and frequency. Frequencies are defined as: **very common (=1/10),** Nasopharyngitis[2,3] ; Headache **common (=1/100 to <1/10),** Candidiasis of the mouth and throat; Pneumonia[1,3]; Bronchitis[1,3]; Hypokalaemia[3]; Throat irritation; Hoarseness/dysphonia; Sinusitis [1,3]; Contusions[1,3]; Muscle cramps; Traumatic fractures Arthralgia[1,3]; Myalgia, **uncommon (=1/1000 to <1/100),** Cutaneous hypersensitivity reactions; Respiratory symptoms (dyspnoea); Hyperglycaemia[4]; Anxiety; Sleep disorders; Tremor; Cataract ; Palpitations; Tachycardia; Atrial fibrillation; Angina pectoris, **rare(=1/10,000 to <1/1000)** Oesophageal candidiasis; Angioedema (mainly facial and oropharyngeal oedema); Respiratory symptoms (bronchospasm); Anaphylactic reactions including anaphylactic shock; Cushing's syndrome, Cushingoid features, Adrenal suppression, Growth retardation in children and adolescents, Decreased bone mineral density[4]; Behavioural changes, including psychomotor hyperactivity and irritability (predominantly in children); Glaucoma [4]; Cardiac arrhythmias (including supraventricular tachycardia and extrasystoles); Paradoxical bronchospasm [4]; and not known (cannot be estimated from the available data) Depression, aggression (predominantly in children). Frequencies were derived from clinical trial data. The incidence in placebo was not taken into account.[1]Reported commonly in placebo, [2]Reported very commonly in placebo. [3]Reported over 3 years in a COPD study [4]See section 4.4 of SmPC. Full description of adverse reactions are detailed in the SmPC**. OVERDOSE:** There are no data available from clinical trials on overdose; however data on overdose with both drugs is provided in section 4.8 & 4.4 of the SmPC. **Date of last SmPC revision:** Dec 2016 **MARKETING AUTHORISATION HOLDER & NUMBER:** Fannin UK Ltd, DCC Vital, Westminster Industrial Estate, Repton Road, Measham, DE12 7DT, England , PA 1585/7/1-2

Legal category POM
REF: IE 17/8/SmPC - November 2016
Date of Update: March 2017

Reporting of suspected adverse reactions

Adverse events should be reported to Fannin Ltd, Pharmacovigilance at +353 868394447 or medical@dccvital.com
Reporting of suspected adverse reactions: Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health care professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace,IRL-Dublin2; Tel: +35316764971; Fax:+35316762517. Website:www.hpra.ie;Email:medsafety@hpra.ie

For a copy of the SmPC or further medical information, please contact medical@DCCvital.com
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GMS Code 36906 = 25 mcg/250 mcg

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