For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only OR for Specialist Use only

Seroflo 50 / 100 Ciphaler

Salmeterol/Fluticasone Propionate 50 Microgram / 100 Microgram Dose Inhalation Powder

Seroflo 50 / 250 Ciphaler

Salmeterol/Fluticasone Propionate 50 Microgram / 250 Microgram Dose Inhalation Powder

Seroflo 50 / 500 Ciphaler

Salmeterol/Fluticasone Propionate 50 Microgram / 500 Microgram Dose Inhalation Powder

COMPOSITION

Seroflo 50 / 100 Ciphaler

Each single inhalation provides a deliver:
Dose (the dose leaving the mouthpiece) of 47 micrograms of salmeterol (as Salmeterol Xinafoate BP/Ph. Eur) and 92 micrograms Fluticasone Propionate BP/Ph. Eur.
This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as Salmeterol Xinafoate BP/Ph. Eur) and 100 micrograms Fluticasone Propionate BP/Ph. Eur.
Also, contains: Lactose Monohydrate.

Seroflo 50 / 250 Ciphaler

Each single inhalation provides a deliver:
Dose (the dose leaving the mouthpiece) of 47 micrograms of salmeterol (as Salmeterol Xinafoate BP/Ph. Eur) and 231 micrograms Fluticasone Propionate BP/Ph. Eur.
This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as Salmeterol Xinafoate BP/Ph. Eur) and 250 micrograms Fluticasone Propionate BP/Ph. Eur.
Also, contains: Lactose Monohydrate.

Seroflo 50 / 500 Ciphaler

Each single inhalation provides a deliver:
Dose (the dose leaving the mouthpiece) of 47 micrograms of salmeterol (as Salmeterol Xinafoate BP/Ph. Eur) and 460 micrograms Fluticasone Propionate BP/Ph. Eur.
This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as Salmeterol Xinafoate BP/Ph. Eur) and 500 micrograms Fluticasone Propionate BP/Ph. Eur.
Also, contains: Lactose Monohydrate.

DOSAGE FORM

Pre dispensed inhalation powder

PRODUCT DESCRIPTION

Bulk Finished Stage

Salmeterol/Fluticasone Propionate Inhalation powder, pre-dispensed BP, is a white to off white powder filled in a strip of 60 blisters**.**

Pack Finished Stage

Device Description

Each carton contains a multi-dose device packaged in a moisture protective foil pouch**.**

Multidose device with numeric dose counter displayed on the top of the device containing blister strip inside.

PHARMACOLOGY

Pharmacodynamics

Pharmacotherapeutic Group: Adrenergics in combination with corticosteroids or other drugs, excl. Anticholinergics.

ATC Code: R03AK06

Mechanism of action and pharmacodynamic effects:

Salmeterol and Fluticasone inhalation powder contains salmeterol and fluticasone propionate which have differing modes of action. The respective mechanisms of action of both drugs are discussed below.

Salmeterol

Salmeterol is a selective long-acting (12 hour) β_2 adrenoceptor agonist with a long side chain which binds to the exo-site of the receptor.

Salmeterol produces a longer duration of bronchodilation, lasting for at least 12 hours, than recommended doses of conventional short-acting β_2 agonists.

Fluticasone propionate

Fluticasone propionate given by inhalation at recommended doses has a glucocorticoid anti-inflammatory action within the lungs, resulting in reduced symptoms and exacerbations of asthma, with less adverse effects than when corticosteroids are administered systemically.

Pharmacokinetics

For pharmacokinetic purposes each component can be considered separately.

Salmeterol

Salmeterol acts locally in the lung therefore plasma levels are not an indication of therapeutic effects. In addition, there are only limited data available on the pharmacokinetics of salmeterol because of the technical difficulty of assaying the drug in plasma due to the low plasma concentrations at therapeutic doses (approximately 200 picogram /mL or less) achieved after inhaled dosing.

Fluticasone propionate

The absolute bioavailability of a single dose of inhaled fluticasone propionate in healthy subjects varies between approximately 5 to 11% of the nominal dose depending on the inhalation device used. In patients with asthma a lesser degree of systemic exposure to inhaled fluticasone propionate has been observed.

Systemic absorption occurs mainly through the lungs and is initially rapid then prolonged. The remainder of the inhaled dose may be swallowed but contributes minimally to systemic exposure due to the low aqueous solubility and pre systemic metabolism, resulting in oral availability of less than 1%. There is a linear increase in systemic exposure with increasing inhaled dose.

The disposition of fluticasone propionate is characterised by high plasma clearance (1150 mL/min), a large volume of distribution at steady-state (approximately 300 L) and a terminal half-life of approximately 8 hours.

Plasma protein binding is 91%.

Fluticasone propionate is cleared very rapidly from the systemic circulation. The main pathway is metabolism to an inactive carboxylic acid metabolite, by the cytochrome P450 enzyme CYP3A4. Other unidentified metabolites are also found in the faeces.

The renal clearance of fluticasone propionate is negligible. Less than 5% of the dose is excreted in urine, mainly as metabolites. The main part of the dose is excreted in faeces as metabolites and unchanged drug.

INDICATIONS

Asthma

Seroflo Ciphaler is indicated in the regular treatment of asthma, including asthma in children and adults, where use of a combination (bronchodilator and inhaled corticosteroid) is appropriate. This may include:

Patients on effective maintenance doses of long-acting beta-agonists and inhaled corticosteroids.

Patients who are symptomatic on current inhaled corticosteroid therapy.

Patients on regular bronchodilator therapy who require inhaled corticosteriods.

Chronic Obstructive Pulmonary Disease (COPD)

Seroflo Ciphaler is indicated for the regular treatment of chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema.

DOSAGE AND METHOD OF ADMINISTRATION

Seroflo Ciphaler is for inhalation only.

Patients should be made aware that Seroflo Ciphaler must be used regularly for optimum benefit, even when asymptomatic.

Asthma

The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. Where the control of symptoms is maintained with twice daily Seroflo, titration to the lowest effective dose could include Seroflo given once daily.

Patients should be given the strength of Seroflo containing the appropriate fluticasone propionate dosage for the severity of their disease.

If a patient is inadequately controlled on inhaled corticosteroid therapy alone, substitution with Seroflo at a therapeutically equivalent corticosteroid dose may results in an improvement in asthma control. For patients whose asthma control is acceptable on inhaled corticosteroid therapy alone, substitution with Seroflo may permit a reduction in corticosteroid dose while maintaining asthma control. For further information, please refer to the ‘Pharmacodynamics’ section.

Recommended Doses:

Adults and adolescents 12 years and older
One inhalation (50 micrograms salmeterol and 100 micrograms fluticasone propionate) twice daily.
or
One inhalation (50 micrograms salmeterol and 250 micrograms fluticasone propionate) twice daily.
or
One inhalation (50 micrograms salmeterol and 500 micrograms fluticasone propionate) twice daily.

Children 4 years and older
One inhalation (50 micrograms salmeterol and 100 micrograms fluticasone propionate) twice daily.
There are no data available for use of Seroflo in children aged under 4 years.

Use of Seroflo for Inhaled Corticosteroid Sparing
Adults and adolescents 12 years and older, with stable asthma who require fluticasone propionate 250 micrograms twice daily or equivalent to maintain control of their asthma; this dose may be replaced with one inhalation (50 micrograms salmeterol and 100 micrograms fluticasone propionate) twice daily.

Chronic Obstructive Pulmonary Disease (COPD)
For adult patients the recommended dose is one inhalation 50/250 micrograms to 50/500 micrograms salmeterol/fluticasone propionate twice daily.

Special patient groups
There is no need to adjust the dose in elderly patients or in those with renal or hepatic impairment.

Using the Seroflo Ciphaler
The device is opened and primed by sliding the lever. The mouthpiece is then placed in the mouth and the lips closed round it. The dose can then be inhaled, and the device closed.

For detailed instructions for use, refer to “Package leaflet: Information for the user”.

CONTRAINDICATIONS

Hypersensitivity to the active substances or to any of the excipients.

WARNINGS AND PRECAUTIONS

Deterioration of disease

Salmeterol and fluticasone inhalation powder 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 salmeterol and fluticasone inhalation powder 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 salmeterol and fluticasone inhalation powder. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation on salmeterol and fluticasone inhalation powder.

Increased requirements for use of reliever medication (short-acting bronchodilators), or decreased response to reliever medication indicate deterioration of control and patients should be reviewed by a physician.

Sudden and progressive deterioration in control of asthma is potentially life-threatening and the patient should undergo urgent medical assessment. Consideration should be given to increasing corticosteroid therapy.

Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose of salmeterol and fluticasone inhalation powder. Regular review of patients as treatment is stepped down is important. The lowest effective dose of salmeterol and fluticasone inhalation powder should be used (see Dosage and Method of Administration).

Treatment with salmeterol and fluticasone inhalation powder should not be stopped abruptly in patients with asthma due to risk of exacerbation. Therapy should be down-titrated under physician supervision.

As with all inhaled medication containing corticosteroids, salmeterol and fluticasone inhalation powder 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.

Cardiovascular effects

Rarely, salmeterol and fluticasone inhalation powder 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 inhalation powder 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.

Hyperglycaemia

There have been very rare reports of increases in blood glucose levels (see Undesirable Effects) and this should be considered when prescribing to patients with a history of diabetes mellitus.

Paradoxical bronchospasm

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. Salmeterol and fluticasone inhalation powder 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 corticosteroid effects

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) (see Paediatric population sub-heading below for information on the systemic effects of inhaled corticosteroids in children and adolescents). **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.

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. 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 Drug Interactions).

Interactions with potent CYP3A4 inhibitors

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 Drug Interactions)*.

Visual disturbance

Visual disturbance may be reported with systemic and topical corticosteroid use. 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 of possible causes, which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Paediatric Population

Children and adolescents <16 years taking high doses of fluticasone propionate (typically ≥ 1000 micrograms/day) may be at particular risk. Systemic effects may occur, particularly at high doses

prescribed for long periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, acute adrenal crisis and growth retardation in children and adolescents and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression. Consideration should be given to referring the child or adolescent to a paediatric respiratory specialist.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroid is regularly monitored. **The dose of inhaled corticosteroid should be reduced to the lowest dose at which effective control of asthma is maintained.**

Lactose intolerance

This medicine contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Pneumonia in patients with COPD

An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies.

There is no conclusive clinical evidence for intra-class differences in the magnitude of the pneumonia risk among inhaled corticosteroid products.

Physicians should remain vigilant for the possible development of pneumonia in patient with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations.

Risk factors for pneumonia in patients with COPD include current smoking status, older age, low body mass index (BMI) and severe COPD.

DRUG INTERACTIONS

β adrenergic blockers may weaken or antagonize the effect of salmeterol. Both non-selective and selective β blockers should be avoided unless there are compelling reasons for their use. 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.

Concomitant use of other β adrenergic containing drugs can have a potentially additive effect.

Fluticasone Propionate

Under normal circumstances, low plasma concentrations of fluticasone propionate are achieved after inhaled dosing, due to extensive first pass metabolism and high systemic clearance mediated by cytochrome CYP3A4 in the gut and liver. Hence, clinically significant drug interactions mediated by fluticasone propionate are unlikely.

Intranasal fluticasone propionate, ritonavir (a highly potent cytochrome CYP3A4 inhibitor) 100 mg b.i.d. increased the fluticasone propionate plasma concentrations several hundred-fold, resulting in markedly reduced serum cortisol concentrations. Information about this interaction is lacking for inhaled fluticasone propionate, but a marked increase in fluticasone propionate plasma levels is expected. Cases of Cushing's syndrome and adrenal suppression have been reported. The combination should be avoided unless the benefit outweighs the increased risk of systemic glucocorticoid side effects.

Slightly less potent CYP3A inhibitor ketoconazole increased the exposure of fluticasone propionate after a single inhalation by 150%. This resulted in a greater reduction of plasma cortisol as compared with fluticasone propionate alone. Co-treatment with other potent CYP3A inhibitors, such as itraconazole and cobicistat-containing products, and moderate CYP3A inhibitors, such as erythromycin, is also expected to increase the systemic fluticasone propionate exposure and the risk of systemic side effects. Combinations 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.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Salmeterol

Potent CYP3A4 inhibitors

Co-administration of ketoconazole (400 mg orally once daily) and salmeterol (50 micrograms inhaled twice daily) resulted in a significant increase in plasma salmeterol exposure. This may lead to an increase in the incidence of other systemic effects of salmeterol treatment (e.g. prolongation of QTc interval and palpitations) compared with salmeterol or ketoconazole treatment alone *(see Warnings and Precautions)*.

Clinically significant effects were not seen on blood pressure, heart rate, blood glucose and blood potassium levels. Co-administration with ketoconazole did not increase the elimination half-life of salmeterol or increase salmeterol accumulation with repeat dosing.
The concomitant administration of ketoconazole should be avoided, unless the benefits outweigh the potentially increased risk of systemic side effects of salmeterol treatment. There is likely to be a similar risk of interaction with other potent CYP3A4 inhibitors (e.g. itraconazole, telithromycin, ritonavir).

Moderate CYP 3A4 inhibitors

Co-administration of erythromycin (500 mg orally three times a day) and salmeterol (50 micrograms inhaled twice daily) resulted in a small but non-statistically significant increase in salmeterol exposure . Co-administration with erythromycin was not associated with any serious adverse effects.

FERTILITY, PREGNANCY AND LACTATION

Fertility

No effects of salmeterol or fluticasone propionate on fertility.

Pregnancy

No malformative or feto/neonatal toxicity related to salmeterol and fluticasone inhalation powder.
Administration of salmeterol and fluticasone inhalation powder to pregnant women should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus.
The lowest effective dose of fluticasone propionate needed to maintain adequate asthma control should be used in the treatment of pregnant women.

Lactation

It is unknown whether salmeterol and fluticasone propionate/metabolites are excreted in human milk.
A risk to breastfed newborns/infants cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue salmeterol and fluticasone inhalation powder therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman.

UNDESIRABLE EFFECTS

As salmeterol and fluticasone inhalation powder 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.

System Organ Class	**Adverse Event**	**Frequency**
Infections & Infestations	Candidiasis of the mouth and throat Bronchitis Pneumonia (in COPD patients) Oesophageal candidiasis	Common Common Common Rare
Immune System Disorders	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	 Uncommon Rare Uncommon Rare Rare
Endocrine Disorders	Cushing's syndrome, Cushingoid features, Adrenal suppression, Growth retardation in children and adolescents, Decreased bone mineral density	Rare
Metabolism & Nutrition Disorders	Hypokalaemia Hyperglycaemia	Common Uncommon
Psychiatric Disorders	Anxiety Sleep disorders Behavioural changes, including psychomotor hyperactivity and irritability (predominantly in children) Depression, aggression (predominantly in children)	Uncommon Uncommon Rare Not Known
Nervous System Disorders	Headache Tremor	Very Common Uncommon
Eye Disorders	Cataract Glaucoma	Uncommon Rare

	Vision, blurred	Not Known
Cardiac Disorders	Palpitations Tachycardia Cardiac arrhythmias (including supraventricular tachycardia and extrasystoles). Atrial fibrillation Angina pectoris	Uncommon Uncommon Rare Uncommon Uncommon
Respiratory, Thoracic & Mediastinal Disorders	Nasopharyngitis Throat irritation Hoarseness/dysphonia Sinusitis Paradoxical bronchospasm	Very Common Common Common Common Rare
Skin and subcutaneous tissue disorders	Contusions	Common
Musculoskeletal & Connective Tissue Disorders	Muscle cramps Traumatic fractures Arthralgia Myalgia	Common Common Common Common

Description of selected adverse reactions

The pharmacological side effects of B_2 agonist treatment, such as tremor, palpitations and headache, have been reported, but tend to be transient and reduce with regular therapy.

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. salmeterol and fluticasone inhalation powder should be discontinued immediately, the patient assessed, and alternative therapy instituted if necessary.

Due to the fluticasone propionate component, hoarseness and candidiasis (thrush) of the mouth and throat and, rarely, of the oesophagus can occur in some patients. Both hoarseness and incidence of mouth and throat candidiasis may be relieved by rinsing the mouth with water and/or brushing the teeth after using the product. Symptomatic mouth and throat candidiasis can be treated with topical anti-fungal therapy whilst still continuing with the salmeterol and fluticasone inhalation powder.

Paediatric population

Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression and growth retardation in children and adolescents *(see Warnings and Precautions)*. Children may also experience anxiety, sleep disorders and behavioural changes, including hyperactivity and irritability.

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. Healthcare professionals are asked to report any suspected adverse reactions via the local reporting system**.**

OVERDOSE

There are no data available on overdose with salmeterol and fluticasone inhalation powder, however data on overdose with both drugs are given below:

The signs and symptoms of salmeterol overdose are dizziness, increases in systolic blood pressure, tremor, headache and tachycardia. If salmeterol and fluticasone inhalation powder therapy has to be withdrawn due to overdose of the β agonist component of the drug, provision of appropriate replacement steroid therapy should be considered. Additionally, hypokalaemia can occur and therefore serum potassium levels should be monitored. Potassium replacement should be considered.

Acute: Acute inhalation of fluticasone propionate doses in excess of those recommended may lead to temporary suppression of adrenal function. This does not need emergency action as adrenal function is recovered in a few days, as verified by plasma cortisol measurements.

Chronic overdose of inhaled fluticasone propionate: Adrenal reserve should be monitored and treatment with a systemic corticosteroid may be necessary. When stabilised, treatment should be continued with an inhaled corticosteroid at the recommended dose. Refer to Warnings and Precautions: risk of adrenal suppression.

In cases of both acute and chronic fluticasone propionate overdose salmeterol and fluticasone inhalation powder therapy should be continued at a suitable dosage for symptom control.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

Salmeterol and fluticasone inhalation powder has no or negligible influence on the ability to drive and use machines.

INSTRUCTION FOR USE

- Your doctor, nurse or pharmacist should show you how to use your Ciphaler. They should check how you use it from time to time. Not using the Salmeterol and Fluticasone Propionate Inhalation Powder properly or as prescribed may mean that it will not help your asthma as it should.
- The Ciphaler holds blisters containing salmeterol and fluticasone as a powder.
- There is a counter on top of the Ciphaler which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in red to warn you when there are only a few doses left. Once the counter shows 0, your inhaler is empty. See Figure A.

Figure A

Using your inhaler

1. To open your Ciphaler, hold the outer case in one hand and put the thumb of your other hand on the thumb grip. Push your thumb away from you as far as it will go. You will hear a click. This will open a small hole in the mouthpiece. See Figure B

Figure B

2. Hold your Ciphaler with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece. See Figure C.

Figure C

Every time the lever is pulled back a blister is opened inside and the powder made ready for you to inhale. Do not play with the lever as this opens the blisters and wastes medicine.

3. Hold the Ciphaler away from your mouth, breathe out as far as is comfortable. Do not breathe into your inhaler. See Figure D.

Figure D

4. Put the mouthpiece to your lips; breathe in steadily and deeply through the inhaler, not through your nose. See Figure E.

- Remove the Ciphaler from your mouth.
- Hold your breath for about 10 seconds or for as long as is comfortable.
- Breathe out slowly.

Figure E

5. Afterwards, rinse your mouth with water and spit it out, and/or brush your teeth. This may help to stop you getting thrush and becoming hoarse. See Figure F.

Figure F

6. To close the Ciphaler, slide the thumb grip back towards you, as far as it will go. You will hear a click. The lever will return to its original position and is reset. See Figure G.

Figure G

Your Ciphaler is now ready for you to use again.
As with all inhalers, caregivers should ensure that children prescribed Salmeterol and Fluticasone Propionate Inhalation Powder use correct inhalation technique, as described above.

Cleaning your Ciphaler
Wipe the mouthpiece of the SEROFLO CIPHALER with a dry tissue to clean it.

INCOMPATIBILITIES
Not applicable

STORAGE
Do not store above 30ºC

SHELF LIFE
24 months

PACKAGING INFORMATION

Each carton contains a multi-dose device packaged in a moisture protective foil pouch**.**

Multidose device with numeric dose counter displayed on the top of the device containing blister strip inside.

PRODUCT REGISTRATION HOLDER

Cipla Malaysia Sdn Bhd.
Suite 1101, Amcorp Tower
Amcorp Trade Centre
18, Persiaran Barat, 46050
Petaling Jaya, Selangor, Malaysia

MANUFACTURER

Cipla Limited
Unit IV, Plot No. 9 & 10,
Indore Special Economic Zone, Phase II, Pithampur,
District Dhar Madhya Pradesh In-454775, India.

DATE OF REVISION

May 2022