Patient Information Leaflet

Information for the Patient about

SEREFLO 25/50 HFA (Inhaler)

SEREFLO 25/125 HFA (Inhaler)

SEREFLO 25/250 HFA (Inhaler)

Read all of this leaflet carefully before you start taking SEREFLO HFA.

- Keep this leaflet; you may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **SEREFLO HFA** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

SEREFLO 25/50 HFA (Inhaler)

SEREFLO 25/125 HFA (Inhaler)

SEREFLO 25/250 HFA (Inhaler)

WHAT SEREFLO HFA CONTAINS:

SEREFLO 25/50 HFA: Each single actuation (puff) provides salmeterol xinafoate equivalent to 25 µg of salmeterol and 50 µg of fluticasone propionate.

SEREFLO 25/125 HFA: Each single actuation provides salmeterol xinafoate equivalent to 25 µg of salmeterol and 125 µg of fluticasone propionate.

SEREFLO 25/250 HFA: Each single actuation provides salmeterol xinafoate equivalent to 25 µg of salmeterol and 250 µg of fluticasone propionate.

Inactive ingredients are anhydrous ethanol, lecithin and norflurane (HFA-134a).

WHAT SEREFLO HFA IS USED FOR:

SEREFLO HFA is used to prevent allergic asthma in children and adults who have been stabilised on identical dosages of the components of **SEREFLO HFA** given in combination.

BEFORE YOU USE SEREFLO HFA:

Do not use SEREFLO HFA if you:

- Are hypersensitive or allergic to fluticasone, salmeterol or any component of this preparation.

Take special care with SEREFLO HFA:

Children who are taking **SEREFLO HFA** may be more susceptible to infections, such as chickenpox or measles. If you or your child is using **SEREFLO HFA**, be careful not to expose yourself or your child to other people with chickenpox or measles.

Tell your doctor if you have any of the following, as you may then require a lower dose or special precaution:

- Pulmonary tuberculosis.
- Overactive thyroid gland (thyrotoxicosis).
- Glaucoma (increased pressure within the eye).
- Cataract.
- Decreased bone mineral density or osteoporosis.
- Growth impairment if you are a teenager.
- Impaired adrenal gland reserve. Your adrenal glands are responsible for your body's own production of corticosteroid hormones, without which one is not able to survive.

You should not discontinue **SEREFLO HFA** without consulting your treating doctor. You should also not discontinue your **SEREFLO HFA** therapy abruptly.

You may experience hoarseness and thrush of the mouth or throat during treatment with **SEREFLO HFA**. In such instances you may find it helpful to gargle with water after using **SEREFLO HFA**. You should also report such symptoms to your doctor, who may decide to prescribe anti-fungal medicines (see **"POSSIBLE SIDE-EFFECTS"**).

You may experience allergic (or hypersensitivity) skin reactions when you use **SEREFLO HFA**.

If you should experience paradoxical (unexpected and contradictory) constriction of your airways with an immediate increase in wheezing or other symptoms of a tight chest after dosing, you should consult your treating doctor immediately.

If you are switching from other inhalation corticosteroids or oral corticosteroids to **SEREFLO HFA**, your adrenal gland reserves may be impaired for a considerable time. You may have to consult a specialist before you schedule elective (non-emergency) surgery. You may have to take additional corticosteroids if your body is going through periods of stress, including medical or surgical emergencies.

If you find your short-acting bronchodilator treatment less effective, or if you need more inhalations than usual, it may indicate that your asthma is not well-controlled. This may be life-threatening and may be due to several causes. In such instances you must consult your treating doctor. He/she may decide to increase your **SEREFLO HFA** dosage or to add additional corticosteroids in the form of tablets.

You may experience systemic side-effects with **SEREFLO HFA**, especially if taken in high doses or for lengthy periods of time. Examples of such effects include suppression of your adrenal glands, growth retardation in children and adolescents, decrease in bone mineral density, cataracts or glaucoma (a condition characterised by raised pressure inside the eye, which may lead to blindness) (see **"POSSIBLE SIDE-EFFECTS"**). Children receiving prolonged treatment should go for regular height assessments with their treating doctor.

Use in pregnancy and breastfeeding:

The safety of **SEREFLO HFA** in pregnancy and lactation (breastfeeding) has not been established. Thus use in pregnancy and lactation is not recommended. Since animal studies have shown that corticosteroids may be harmful to developing foetuses, it cannot be excluded that inhalation therapy with corticosteroids will not harm your baby.

If you are pregnant or breastfeeding your baby while taking SEREFLO HFA, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

SEREFLO HFA is unlikely to produce an effect. However, some patients may experience dizziness. If you experience dizziness, you should refrain from driving or operating machinery to avoid accidents from occurring.

Use in elderly:

There is no need to adjust the dose in elderly patients or those with liver or kidney impairment.

Taking other medicines with SEREFLO HFA:

Clinically significant interactions with other medications are unlikely. If you are taking other medicines on a regular basis, including complementary or traditional medicines, use of **SEREFLO HFA** with other medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

In particular, please tell your doctor or pharmacist if you are taking:

- Ketoconazole for the treatment of fungal infections or ritonavir for the treatment of HIV infection, since these medicines may increase blood levels of fluticasone propionate.
- Beta-blockers, for high blood pressure or abnormal heart rhythm.

HOW TO USE SEREFLO HFA:

Always use SEREFLO HFA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual daily dose of **SEREFLO HFA** is as follows:

Two inhalations of **SEREFLO 25/50 HFA** twice daily (morning and evening),

OR

Two inhalations of **SEREFLO 25/125 HFA** twice daily (morning and evening),

OR

Two inhalations of **SEREFLO 25/250 HFA** twice daily (morning and evening).

You must use **SEREFLO HFA** regularly for optimum benefit, even if you do not experience symptoms, such as shortness of breath. You have to go for regular examinations to your treating doctor so that he/she can ensure that you are receiving the optimal dose of **SEREFLO HFA**.

SEREFLO HFA is not designed to relieve acute asthma symptoms for which an inhaled fast and short-acting beta$_2$-stimulant or bronchodilator is required. You

should always have such rescue medication available. In such instances you must consult your treating doctor.

If you use more SEREFLO HFA than you should:

In the event of an overdosage, or if someone else has taken your medicine by mistake, side-effects that may be experienced due to salmeterol, are tremor, headache or palpitations. In the event of an overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use SEREFLO HFA:

Use **SEREFLO HFA** as prescribed. If you miss a dose of this medicine, take it as soon as possible. However, if you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not use a double dose to compensate for the forgotten individual dose.

Effects when treatment with SEREFLO HFA is stopped:

Please consult your doctor before abruptly discontinuing **SEREFLO HFA** as your doctor will advise you on the tapered dose to minimise the risk of discontinuation symptoms.

POSSIBLE SIDE-EFFECTS:

SEREFLO HFA may have unintended or undesirable effects. Not all side-effects reported for **SEREFLO HFA** are included in this leaflet. Should your general health

worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side-effects reported with the use of **SEREFLO HFA** include, but are not limited to:

- Hypersensitivity or allergic reactions, such as rash with or without hives, swelling, which may be severe, and difficulty breathing. Please contact your doctor immediately if you experience any of these symptoms.
- Unexpected bronchospasm (tight chest). Should you experience shortness of breath or tightness of your chest after using **SEREFLO HFA**, please contact your treating doctor as a matter of urgency.
- Difficulty breathing or a sensation of choking.
- Raised pressure inside the eye characterised by eye pain, red eyes and blurred vision or deterioration in vision. Please report such symptoms to your doctor immediately.
- Inflammation of the membrane covering the pupil of the eye characterised by eye pain, sensitivity to light, discharge, red eyes and sometimes by fever and headache. Please report to your doctor immediately.

Other side-effects that you may experience with **SEREFLO HFA** and that you should report to your doctor as soon as possible, include:

- Thrush of the mouth or throat as well as vaginal thrush.
- Flu-like symptoms or other symptoms of respiratory tract infection or a sore throat.

- Pain over the sinuses accompanied by blocked nose, headache or runny nose.
- Redistribution of body fat with the development of a hump over the back of the neck, moon face and fat over the abdomen.
- Vision disturbances or blurred vision.
- Ear pain, sometimes accompanied by fever, nausea or dizziness.
- Pelvic pain or menstrual disturbances.

Please report the following side-effects to your doctor when they continue or become bothersome:

- Palpitations.
- Anxiety, aggression, depression or restlessness.
- Dizziness, giddiness.
- Muscle cramps or pain and joint pain.
- Tremor or headache, including migraine.
- Anxiety, sleep disorders, including sleeplessness, and behavioural changes, as well as nervousness and pins and needles or abnormal sensation in the hands or feet.
- Eye irritation or inflammation of the membrane covering the white of the eye.
- Hoarseness, throat irritation or sneezing.
- Nose bleeds, coughing or runny nose.
- Runny stomach (diarrhoea), stomach pain, discomfort or cramps.
- Nausea.
- Weight gain.
- Skin disorders, such as itching (pruritus), or bruises.

- Generally feeling unwell or fatigue.

Hoarseness and candidiasis (thrush) of the mouth and throat can occur. Patients who experience hoarseness and candidiasis (thrush) of the mouth and throat may find it helpful to gargle with water after using **SEREFLO HFA**. If you suffer from thrush, your doctor may prescribe a topical anti-fungal antibiotic whilst you continue using **SEREFLO HFA**.

While receiving treatment with **SEREFLO HFA**, you may develop:

- Low blood potassium levels.
- Growth retardation if you are a child or adolescent (your doctor will monitor you for this).
- Decreased bone mineral density.

STORAGE AND DISPOSING OF SEREFLO HFA:

KEEP OUT OF REACH OF CHILDREN.

Store in a cool dry place, at or below 25 ºC.

Avoid storage in direct sunlight and heat.

The canister is pressurised; it should not be broken, punctured or burnt, even when apparently empty.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF SEREFLO HFA:

SEREFLO 25/50 HFA: Carton containing a pressurised aluminium container with a plastic actuator, with or without a long mouthpiece plastic actuator (Gentle-Haler); or a pressurised aluminium container sealed inside a breath-activated plastic actuator with a dose counter (Synchrobreathe). Each container provides 120 metered dose inhalations.

SEREFLO 25/125 HFA: Carton containing a pressurised aluminium container with a plastic actuator, with or without a long mouthpiece plastic actuator (Gentle-Haler); or a pressurised aluminium container sealed inside a breath-activated plastic actuator with a dose counter (Synchrobreathe). Each container provides 120 metered dose inhalations.

SEREFLO 25/250 HFA: Carton containing a pressurised aluminium container with a plastic actuator, with or without a long mouthpiece plastic actuator (Gentle-Haler); or a pressurised aluminium container sealed inside a breath-activated plastic actuator with a dose counter (Synchrobreathe). Each container provides 120 metered dose inhalations.

IDENTIFICATION OF SEREFLO HFA:

SEREFLO 25/50 HFA: A white homogenous suspension aerosol for inhalation.

SEREFLO 25/125 HFA: A white homogenous suspension aerosol for inhalation.

SEREFLO 25/250 HFA: A white homogenous suspension aerosol for inhalation.

REGISTRATION NUMBERS:

SEREFLO 25/50 HFA: 42/21.5.4/0218

SEREFLO 25/125 HFA: 42/21.5.4/0219

SEREFLO 25/250 HFA: 42/21.5.4/0220

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

Cipla Medpro (Pty) Ltd

Rosen Heights

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Rosen Park

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