PATIENT INFORMATION LEAFLET FOR

SEREFLO DPI

SCHEDULING STATUS: S4

SEREFLO DPI 50/100 micrograms / dose inhalation powder, pre-dispensed

SEREFLO DPI 50/250 micrograms / dose inhalation powder, pre-dispensed

SEREFLO DPI 50/500 micrograms / dose inhalation powder, pre-dispensed

Salmeterol and fluticasone propionate

Contains sugar: lactose monohydrate

Each dose of SEREFLO DPI 50/100 contains 12,32 mg of lactose monohydrate

Each dose of SEREFLO DPI 50/250 contains 12,18 mg of lactose monohydrate

Each dose of SEREFLO DPI 50/500 contains 11,92 mg of lactose monohydrate

Read all of this leaflet carefully before you start using SEREFLO DPI

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SEREFLO DPI 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.

What is in this leaflet

1. What SEREFLO DPI is and what it is used for
2. What you need to know before you use SEREFLO DPI
3. How to use SEREFLO DPI
4. Possible side effects

5. How to store SEREFLO DPI
6. Contents of the pack and other information.

1. What SEREFLO DPI is and what it is used for

SEREFLO DPI contains two medicines, salmeterol and fluticasone propionate:

- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out.
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

SEREFLO DPI is used to prevent breathing problems such as:

- Asthma
- Chronic Obstructive Pulmonary Disease (COPD).

2. What you need to know before you use SEREFLO DPI

Do not use SEREFLO DPI if you

- are hypersensitive or allergic to fluticasone, salmeterol or any of the other ingredients of SEREFLO DPI (listed in **section 6**).

Warnings and precautions

Take special care with SEREFLO DPI:

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

- Pulmonary tuberculosis.
- Overactive thyroid gland (hyperthyroidism).
- Glaucoma (increased pressure within the eye).
- Cataract.

- 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.
- Using an intra-uterine device for contraception.
- Increased blood sugar level.
- Paradoxical bronchospasm (sudden constriction of the muscles in the walls of the bronchioles), with an immediate increase in wheezing and shortness of breath after dosing.
- Pneumonia (an infection that inflames the air sacs in one or both lungs).

You should not stop using SEREFLO DPI without consulting your treating doctor. You should also not stop using your SEREFLO DPI therapy abruptly.

You may experience hoarseness and thrush of the mouth or throat during treatment with SEREFLO DPI. In such instances you may find it helpful to gargle with water after using SEREFLO DPI. You should also report such symptoms to your doctor, who may decide to prescribe anti-fungal medicines (see **section 4)**.

You may experience allergic (or hypersensitivity) skin reactions when you use SEREFLO DPI.
If you are switching from other inhalation corticosteroids or oral corticosteroids to SEREFLO DPI, 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 DPI dosage or to add additional corticosteroids in the form of tablets.

You may experience systemic side effects with SEREFLO DPI, 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 **section 4)**. Children receiving prolonged treatment should go for regular height assessments with their treating doctor.

Other medicines and SEREFLO DPI

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

If you are taking other medicines on a regular basis, including complementary or traditional medicines, use of SEREFLO DPI with other medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care provider for advice.

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

- Beta-blockers, for high blood pressure or abnormal heart rhythm.

Pregnancy, breastfeeding and fertility

The safety of SEREFLO DPI 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, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using SEREFLO DPI.

Driving and using machines

Since SEREFLO DPI may cause blurred vision or deterioration of vision (see **section 4**), the ability to drive and use machines may be negatively affected.

It is not always possible to predict to what extent SEREFLO DPI may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which SEREFLO DPI affects you.

SEREFLO DPI contains lactose

SEREFLO DPI contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

3. How to use SEREFLO DPI

Do not share medicines prescribed for you with any other person.

Always use SEREFLO DPI exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Asthma:

The usual daily dose of SEREFLO DPI is as follows:

Adults and adolescents 12 years and older:

One inhalation SEREFLO DPI 50/100 twice daily, or

One inhalation SEREFLO DPI 50/250 twice daily, or

One inhalation SEREFLO DPI 50/500 twice daily.

Children 4 years and older

One inhalation SEREFLO DPI 50/100 twice daily.

There are no data available for the use of SEREFLO DPI in children under 4 years.

Chronic Obstructive Pulmonary Disease (COPD):

For adult patients the recommended dose is one inhalation SEREFLO DPI 50/250 or one inhalation SEREFLO DPI 50/500 twice daily.

Use in elderly:

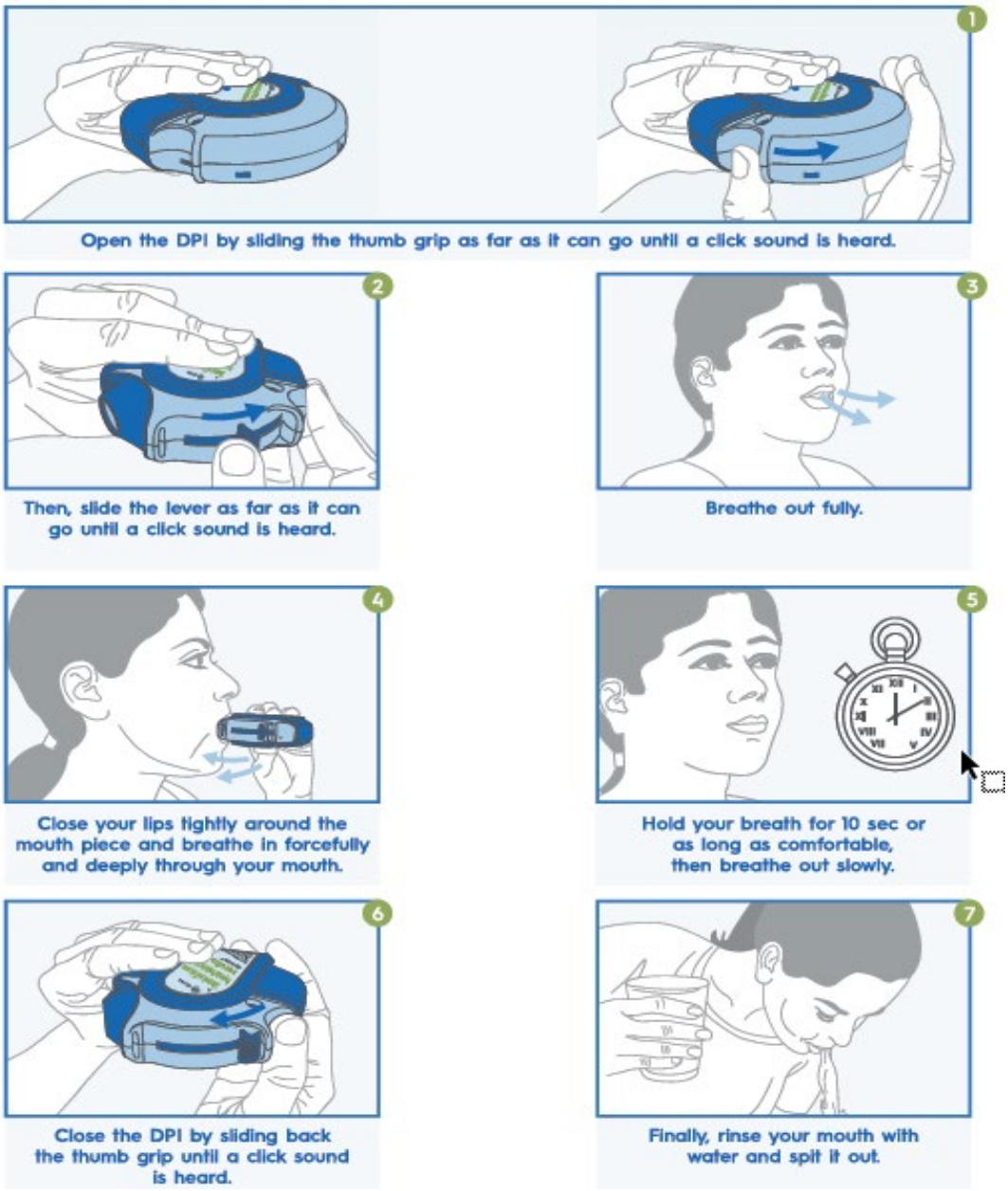
There is no need to adjust the dose in elderly patients or those with liver or kidney impairment.

You must use SEREFLO DPI 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 DPI.

Your doctor will tell you how long your treatment with SEREFLO DPI will last.

If you have the impression that the effect of SEREFLO DPI is too strong or too weak, tell your doctor or pharmacist.

Instructions on how to use SEREFLO DPI inhaler



If you use more SEREFLO DPI than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Side effects that may be experienced due to salmeterol overdosage, are tremors, headaches or palpitations.

If you forget to use SEREFLO DPI

Use SEREFLO DPI as prescribed. Do not take a double dose to make up for ~~a~~ forgotten individual doses. Just take your next dose at the usual time.

If you stop using SEREFLO DPI

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

4. Possible side effects

SEREFLO DPI can have side effects. Not all side effects reported for SEREFLO DPI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SEREFLO DPI, please consult your health care provider for advice.

If any of the following happens, stop using SEREFLO DPI and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,

These are all very serious side effects. If you have them, you may have had a serious reaction to SEREFLO DPI. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- unexpected bronchospasm (tight chest),
- 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,

- 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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- thrush of the mouth or throat,
- flu-like symptoms, infections or other symptoms of respiratory tract infection or a sore throat,
- pain over the sinuses accompanied by blocked nose, headache or runny nose,
- pelvic pain or menstrual disturbances.
- palpitations,
- anxiety, aggression, depression or restlessness, irritability in children
- muscle cramps or pain and joint pain,
- tremor or headache, including migraine,
- hoarseness, throat irritation,
- sneezing, coughing or runny nose,
- weight gain,
- skin disorders, such as excessive sweating, excessive hair growth, skin thinning or bruises,
- low blood potassium levels and high glucose levels,
- growth retardation if you are a child or adolescent (your doctor will monitor you for this).
- decreased bone mineral density.
- abnormal heart rhythms, cardiac failure
- high blood pressure
- peptic ulcers

- symptoms of stomach pain, nausea vomiting, cramps or seizures (tumour lysis syndrome)
- symptoms of upper abdominal pain, nausea, vomiting, pain that feels worse after eating, fever (acute pancreatitis)
- symptoms of muscle weakness and feeling tired, loss of appetite and weight loss, darkening of skin and stomach pain (adrenal atrophy)
- symptoms such as back pain, bone fractures that happen more easily (osteoporosis) and bone pain (avascular necrosis of bone).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of SEREFLO DPI.

5. How to store SEREFLO DPI

Store all medicines out of reach of children.

Store at or below 25 ºC.

Store in the original container.

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What SEREFLO DPI contains

The active substances are salmeterol and fluticasone propionate.

SEREFLO DPI 50/100: Each single actuation (puff) provides salmeterol xinafoate equivalent to 50 micrograms of salmeterol and 100 micrograms of fluticasone propionate.

SEREFLO DPI 50/250: Each single actuation (puff) provides salmeterol xinafoate equivalent to 50 micrograms of salmeterol and 250 micrograms of fluticasone propionate.

SEREFLO DPI 50/500: Each single actuation (puff) provides salmeterol xinafoate equivalent to 50 micrograms of salmeterol and 500 micrograms of fluticasone propionate.

The other ingredient is lactose monohydrate.

What SEREFLO DPI looks like and contents of the pack

Contents of the pack

The inhalation powder is contained in a plastic inhaler containing a foil blister strip with a peelable foil laminate lid containing 60 blisters. The inhaler has a numeric dose counter displayed on the top of the device which indicates the number of doses left. The inhaler is packaged in a plastic-coated, moisture protective foil pouch.

What SEREFLO DPI looks like

SEREFLO DPI 50/100: is a white to off white powder filled in a strip of 60 blisters for inhalation.

SEREFLO DPI 50/250: is a white to off white powder filled in a strip of 60 blisters for inhalation.

SEREFLO DPI 50/500: is a white to off white powder filled in a strip of 60 blisters for inhalation.

Holder of Certificate of Registration

Cipla Medpro (Pty) Ltd.

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Bellville, 7530

Customer Care: 080 222 6662

This leaflet was last revised in

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SEREFLO DPI 50/100: 54/21.5.1/0111.109

SEREFLO DPI 50/250: 54/21.5.1/0112.110

SEREFLO DPI 50/500: 56/21.5.1/0069.068

Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated and included after approval.