

# SEROFLO CIPHALER

Salmeterol / Fluticasone propionate (50/100, 50/250, 50/500 micrograms)

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## **What SEROFLO is used for**

The doctor has prescribed this medicine to help with breathing problems in patients who need regular treatment.

Asthma is a long-term condition affecting the lungs. Symptoms of asthma include shortness of breath, wheezing, chest tightness and cough. Two main causes of asthma symptoms are bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

Chronic obstructive pulmonary disease (COPD) is a long-term, progressively worsening condition affecting the lungs, results from chronic bronchitis or emphysema (linings of the air sacs in the lungs damaged beyond repair).

## **How SEROFLO works**

SEROFLO 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. The effects last for at least 12 hours
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs.

SEROFLO helps to stop breathlessness and wheeziness coming on.

## **Before you use SEROFLO**

### -When you must not use it

Do not use SEROFLO to relieve a sudden attack of breathlessness or wheezing. If this happens you need to use a fast-acting 'reliever' ('rescue') inhaler, such as salbutamol. You should always have your fast acting 'rescue' inhaler with you.

Do not take SEROFLO: If you are allergic to salmeterol, fluticasone propionate or to the other ingredient, such as lactose monohydrate.

### -Before you start to use it

Talk to your doctor before using SEROFLO if you have:

- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (SEROFLO may increase your blood sugar)
- Low potassium in your blood
- Tuberculosis (TB) now or in the past, or other lung infections.
- Pregnant or likely to become pregnant, breast-feeding.

Contact your doctor if you experience blurred vision or other visual disturbances.

### -Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines including medicines for asthma or any medicines obtained without a prescription. This is because SEROFLO may not be suitable to be taken with some other medicines.

Tell your doctor if you are taking the following medicines, before starting to use SEROFLO:

- $\beta$  blockers (such as atenolol, propranolol and sotalol).  $\beta$  blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (such as ketoconazole, itraconazole and erythromycin) including some medicines for HIV treatment (such as ritonavir, cobicistat containing

products). Some of these medicines may increase the amount of fluticasone propionate or salmeterol in your body. This can increase your risk of experiencing side effects with SEROFLO including irregular heartbeats or may make side effects worse. Your doctor may wish to monitor you carefully if you are taking these medicines.

- Corticosteroids (by mouth or by injection). If you have had these medicines recently, this might increase the risk of this medicine affecting your adrenal gland.
- Diuretics, also known as 'water tablets' used to treat high blood pressure.
- Other bronchodilators (such as salbutamol).
- Xanthine medicines. These are often used to treat asthma

Some medicines may increase the effects of SEROFLO and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

## **How to use SEROFLO**

### -How much to use

The medicine in SEROFLO should be inhaled into your lungs. You may not be able to taste or feel the powder on your tongue if you have used the Ciphaler correctly.

SEROFLO must be inhaled through the mouth.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

## **Asthma**

### **Adults and adolescents aged 12 years and older:**

- SEROFLO 50/100 CIPHALER - One inhalation twice a day
- SEROFLO 50/250 CIPHALER - One inhalation twice a day

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- SEROFLO 50/500 CIPHALER - One inhalation twice a day

## Children 4 years and older:

- SEROFLO 50/100 CIPHALER - One inhalation twice a day
- SEROFLO CIPHALER is not recommended for use in children below 4 years of age

## COPD

### Adult patients

One inhalation of 50/250 mcg to 50/500 mcg twice daily.

### If your asthma or breathing gets worse tell your doctor straight away.

You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast-acting 'reliever' medicine. If any of these happen, you should continue to take SEROFLO but do not increase the number of puffs you take. Your chest condition may be getting worse and you could become seriously ill. See your doctor as you may need additional treatment.

### Instructions 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 Ciphaler 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 Ciphaler is empty. See Figure A.



Figure A

### Using your Ciphaler

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 Ciphaler. See Figure D.



Figure D

4. Put the mouthpiece to your lips; breathe in steadily and deeply through the Ciphaler, 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

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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 SEROFLO use correct inhalation technique, as described above.

## Cleaning your Ciphaler

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

### -When to use it

Use SEROFLO every day until your doctor advises you to stop. Do not take more than the recommended dose. Check with your doctor or pharmacist if you are not sure.

### -How long to use it

It is very important that you take your SEROFLO every day as directed. Keep taking it until your doctor tells you to stop even if you have no symptoms.

### -If you forget to use it

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

### -If you use too much (overdose)

It is important to use the inhaler as instructed. If you accidentally take a larger dose than recommended, talk to your doctor or pharmacist. You may notice your heart beating faster than usual and that you feel shaky. You may also have dizziness, a headache, muscle weakness and aching joints. If you have used larger doses for a long period of time, you should talk to your doctor or pharmacist for advice. This is because

larger doses of SEROFLO may reduce the amount of steroid hormones produced by the adrenal gland.

## While you are using it

### -Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor

### -Things you must not do

Do not:

- Stop taking the medicine unless advised by your doctor.
- Take any new medicines without consulting your doctor.
- Give this medicine to anyone else, even if they have the same symptoms or condition as you.

### -Things to be careful of

If you are breathless or wheezing more often than normal, tell your doctor.

## Side Effects

Any medicine which contains corticosteroids may have some effect on patients. This is far more common when patients are taking oral corticosteroids. These effects are not usually seen with inhaled corticosteroids but can occur in patients taking high doses for a long time. It is possible that these patients may experience: loss of bone density, eye problems, slowing of growth in children. Consult your doctor if you are worried about yourself or your children.

Most people taking this medicine find that it causes no problems. As with all medicines, a few people may find that it causes side effects. Some people can be allergic to medicines. If you have any of the following symptoms soon after taking SEROFLO, STOP taking this medicine and tell your doctor immediately.

- Sudden wheeziness and chest pain or tightness

- Swelling of eyelids, face, lips, tongue or throat
- Lumpy skin rash or “hives” anywhere on the body

Some people may develop hoarseness, difficulty swallowing or thrush (candidiasis) in their mouth or throat and, rarely in their oesophagus. Rinsing with water and spitting it out immediately after each dose may help. Tell your doctor but do not stop treatment unless told to do so. Also tell your doctor if you have any of the following symptoms: headache, muscle cramps, pains in joints, skin rash or trembling, increase in pulse rate.

It is possible that some patients, particularly those taking higher doses of this type of medication, may very rarely suffer from the following side effects: Rounded face, loss of bone density, eye problems and slowing of growth in children.

Some patients may experience increased bruising.

There may be an increase in the amount of sugar (glucose) in your blood. If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetes treatment may be required.

Very rarely the person taking the medicine may feel anxious, have disturbed sleep or notice increase irritability (mainly in children).

### Pneumonia (infection of the lung) in COPD patients (common side effect)

Tell your doctor if you have any of the following while taking SEROFLO. They could be symptoms of a lung infection:

- Fever or chills
- Increased mucus production or change in mucus colour;
- Increased cough or increased breathing difficulties

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If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

## Reporting of side effects

You may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers ->Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of SEROFLO

### -Storage

- **Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.

### -Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

## Product Description

### -What it looks like

#### Description

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

#### 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.

### -Ingredients

#### Active ingredient

Salmeterol (as salmeterol xinafoate) and Fluticasone propionate

#### Inactive ingredients

Lactose Monohydrate

### -MAL Number

SEROFLO 50/100 CIPHALER

MAL21116022AZ

SEROFLO 50/250 CIPHALER

MAL21116023AZ

SEROFLO 50/500 CIPHALER

MALXXXXXXXXXAZ

#### Manufacturer

Cipla Limited  
Unit IV, Plot No. 9 & 10,  
Indore Special Economic Phase,  
Phase II, Pithampur,  
District Dhar Madhya Pradesh In -  
454 775, India.

#### Product Registration Holder

CIPLA MALAYSIA SDN BHD  
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15/02/2023

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