Package leaflet: Information for the user

Salmeterol/Flutikason Cipla 50 microgram / 250 microgram per dose inhalation powder, predispensed
Salmeterol/Flutikason Cipla 50 microgram / 500 microgram per dose inhalation powder, predispensed

salmeterol/fluticasone propionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms and signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for

<Invented name> 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.

The doctor has prescribed this medicine to help prevent breathing problems such as:
- Asthma
- Chronic Obstructive Pulmonary Disease (COPD). Salmeterol and fluticasone propionate, at a dose of 50/500 micrograms, reduces the number of flare ups of COPD symptoms.

You must use <Invented name> every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

<Invented name> helps to stop breathlessness and wheeziness coming on. However <Invented name> should not be used 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.

2. What you need to know before you use <Invented name>

Do not use <Invented name>:
If you are allergic to salmeterol, fluticasone propionate or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before using <Invented name> if you have:
- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (<Invented name> may increase your blood sugar)
- Low potassium in your blood
- Tuberculosis (TB) now or in the past, or other lung infections

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

Children and adolescents
<Invented name> should not be used in children under 12 years of age.

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines including medicines for asthma or any medicines obtained without a prescription. This is because <Invented name> may not be suitable to be used with some other medicines.

Tell your doctor if you are taking the following medicines, before starting to use <Invented name>:
- β blockers (such as atenolol, propranolol and sotalol). β 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 <Invented name>, including irregular heart beats, 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.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
<Invented name> is not likely to affect your ability to drive or use machines unless you get side effects such as blurred vision.

<Invented name> contains lactose
This medicine contains lactose up to 12 mg of lactose monohydrate in each dose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The excipient lactose monohydrate contains small amounts of milk proteins, which may cause allergic reactions.

3. How to use <Invented name>

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

- Use your <Invented name> 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.
- Do not stop taking <Invented name> or reduce the dose of <Invented name> without talking to your doctor first.
- <Invented name> should be inhaled through the mouth into the lungs.
- You may not be able to taste or feel the powder on your tongue, even if you have used the inhaler correctly.

For asthma

Adults and adolescents aged 12 years and over
- <Invented name> 50 micrograms/250 micrograms - One inhalation twice a day
- <Invented name> 50 micrograms/500 micrograms - One inhalation twice a day

Use in children
<Invented name> is **not** recommended for use in children below 12 years of age.

For adults with Chronic Obstructive Pulmonary Disease (COPD)
- <Invented name> 50 micrograms/500 micrograms - One inhalation twice a day

Your symptoms may become well controlled using <Invented name> twice a day. If so, your doctor may decide to reduce your dose to once a day. The dose may change to:
- once at night - if you have **night-time** symptoms
- once in the morning - if you have **daytime** symptoms.

It is very important to follow your doctor's instructions on how many inhalations to take and how often to take your medicine.

If you are using <Invented name> for asthma, your doctor will want to regularly check your symptoms.

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 <Invented name> 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 inhaler. They should check how you use it from time to time. Not using the <Invented name> properly or as prescribed may mean that it will not help your asthma or COPD as it should.
- The inhaler device holds blisters containing <Invented name> as a powder.

- There is a counter on top of the inhaler which tells you how many doses are left. See Figure A. 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.

Figure A

Using your inhaler

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

Figure B

2. Hold your inhaler 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. See Figure C. You will hear a click. This places a dose of your medicine in the mouthpiece. 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.

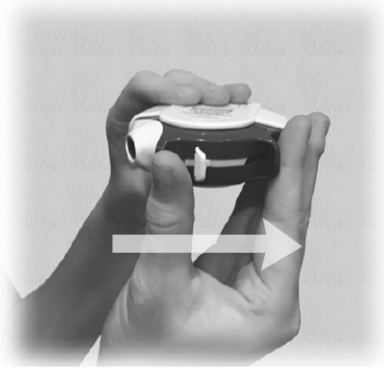

Figure C

3. Hold the inhaler 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 inhaler 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.

6. To close the inhaler, slide the thumbgrip 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 F. Your inhaler is now ready for you to use again.

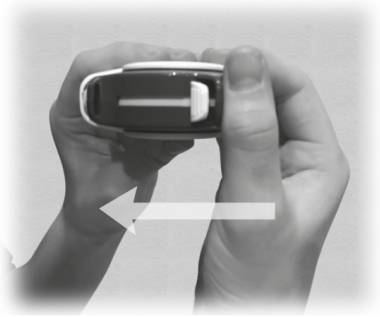

Figure F

As with all inhalers, caregivers should ensure that children prescribed <Invented name> use correct inhalation technique, as described above.

Cleaning your inhaler
Wipe the mouthpiece of the <Invented name> with a dry tissue to clean it.

If you use more <Invented name> than you should
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 <Invented name> may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use <Invented name>
Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop using <Invented name>
It is very important that you take your <Invented name> every day as directed. **Keep taking it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of <Invented name>.** This could make your breathing worse.

In addition, if you suddenly stop taking <Invented name> or reduce your dose of <Invented name> this may (very rarely) cause you to have problems with your adrenal gland (adrenal insufficiency) which sometimes causes side effects.

These side effects may include any of the following:
- Stomach pain
- Tiredness and loss of appetite, feeling sick
- Sickness and diarrhoea
- Weight loss
- Headache or drowsiness
- Low levels of sugar in your blood
- Low blood pressure and seizures (fits)

When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse and you may have any of the side effects listed above.

If you get any side effects, talk to your doctor or pharmacist. To prevent these symptoms occurring, your doctor may prescribe extra corticosteroids in tablet form (such as prednisolone).

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. To reduce the chance of side effects, your doctor will prescribe the lowest dose of <Invented name> to control your asthma or COPD.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using <Invented name>. You may be very wheezy and cough or be short of breath. You may also notice itching, a rash (hives) and swelling (usually of the face, lips, tongue, or throat), or you may suddenly feel that your heart is beating very fast or you feel faint and light headed (which may lead to collapse or loss of consciousness). **If you get any of these effects or if they happen suddenly after using**

<Invented name>, stop using <Invented name> and tell your doctor straight away. Allergic reactions to <Invented name> are uncommon (may affect up to 1 in 100 people).

Pneumonia (infection of the lung) in COPD patients. (Common side effect)

Tell your doctor if you have any of the following while taking <Invented name> they could be symptoms of a lung infection:
- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties

Other side effects are listed below:

Very Common (may affect more than 1 in 10 people)
- Headache - this usually gets better as treatment continues.
- Increased number of colds have been reported in patients with COPD.

Common (may affect up to 1 in 10 people)
- Thrush (sore, creamy-yellow, raised patches) in the mouth and throat. Also sore tongue and hoarse voice and throat irritation. Rinsing your mouth out with water and spitting it out immediately and/or brushing your teeth after taking each dose of your medicine may help. Your doctor may prescribe an anti-fungal medication to treat the thrush.
- Aching, swollen joints and muscle pain.
- Muscle cramps.

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):
- Bruising and fractures.
- Inflammation of sinuses (a feeling of tension or fullness in the nose, cheeks and behind the eyes, sometimes with a throbbing ache).
- A reduction in the amount of potassium in the blood (you may get an uneven heart beat, muscle weakness, cramp).

Uncommon (may affect up to 1 in 100 people)
- Increases in the amount of sugar (glucose) in your blood (hyperglycaemia). If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetic treatment may be required.
- Cataract (cloudy lens in the eye).
- Very fast heart beat (tachycardia).
- Feeling shaky (tremor) and fast or uneven heart beat (palpitations) - these are usually harmless and get less as treatment continues.
- Chest pain.
- Feeling worried (this effect mainly occurs in children).
- Disturbed sleep.
- Allergic skin rash.

Rare (may affect up to 1 in 1,000 people)
- **Breathing difficulties or wheezing that get worse straight after taking <Invented name>.** If this happens **stop using your <Invented name> inhaler**. Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away**.
- <Invented name> may affect the normal production of steroid hormones in the body, particularly if you have taken high doses for long periods of time. The effects include:
  - Slowing of growth in children and adolescents
  - Thinning of the bones
  - Glaucoma
  - Weight gain

– Rounded (moon shaped) face (Cushing's Syndrome)

Your doctor will check you regularly for any of these side effects and make sure you are taking the lowest dose of <Invented name> to control your asthma.

- Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
- Uneven heart beat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking <Invented name> unless the doctor tells you to stop.
- A fungal infection in the oesophagus (gullet), which might cause difficulties in swallowing.

Not known (frequency cannot be estimated from the available data):

- Depression or aggression. These effects are more likely to occur in children.
- Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

- 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 refrigerate or freeze.
- Once a foil pouch has been opened, the medicine inside should be used within 2 months. Store the open inhaler below 25°C.
- 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.

6. Contents of the pack and other information

What <Invented name> contains

- The active substances are salmeterol and fluticasone propionate. Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 47 micrograms of salmeterol (as salmeterol xinafoate) and 231 or 460 micrograms of fluticasone propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 250 or 500 micrograms fluticasone propionate.
- The other ingredient is lactose monohydrate (which contains milk proteins). See section 2.

What <Invented name> looks like and contents of the pack

- The <Invented name> are supplied as a disposable rubine red-white plastic inhaler containing a blister strip with 60 regularly placed blisters. The blister contains a white to off-white powder. The blister consists of forming foil (OPA/ALU/PVC) and lidding foil (PAPER / PET/ALU/HSL). The inhaler is packaged in a laminated aluminium foil pouch (PET / PE /Alu Foil / PE).
- Each dose is pre-dispensed.

<Invented name> is available in packs containing 1 inhaler. Each inhaler contains 60 inhalations.

Marketing Authorisation Holder and manufacturer

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer
<To be completed nationally>

This medicinal product is authorised in the Member States of the EEA under the following names:
< {Name of the Member State}> < {Name of the Medicinal Product}>
<To be completed nationally>

This leaflet was last revised 2025-11-17