

## Package leaflet: Information for the user

**Salmeterol/Fluticasone 50 microgram/100 microgram/dose inhalation powder, pre-dispensed**  
**Salmeterol/Fluticasone 50 microgram/250 microgram/dose inhalation powder, pre-dispensed**  
**Salmeterol/Fluticasone 50 microgram/500 microgram/dose inhalation powder, pre-dispensed**  
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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What Salmeterol/Fluticasone is and what it is used for
2. What you need to know before you use Salmeterol/Fluticasone
3. How to use Salmeterol/Fluticasone
4. Possible side effects
5. How to store Salmeterol/Fluticasone
6. Contents of the pack and other information

### **1. What Salmeterol/Fluticasone is and what it is used for**

Salmeterol/Fluticasone 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/Fluticasone, at a dose of 50/500 micrograms, reduces the number of flare ups of COPD symptoms.

You must use Salmeterol/Fluticasone every day as directed by your doctor. This will make sure that it works properly in controlling your asthma or COPD.

**Salmeterol/Fluticasone helps to stop breathlessness and wheeziness coming on. However Salmeterol/Fluticasone 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 fastacting 'rescue' inhaler with you.**

### **2. What you need to know before you use Salmeterol/Fluticasone**

#### **Do not use Salmeterol/Fluticasone**

If you are allergic to salmeterol, fluticasone propionate or to the other ingredient lactose monohydrate.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Salmeterol/Fluticasone, if you have:

- heart disease, including an irregular or fast heart beat

- overactive thyroid gland
- high blood pressure
- diabetes mellitus (Salmeterol/Fluticasone 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.

### **Other medicines and Salmeterol/Fluticasone**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines for asthma or any medicines obtained without a prescription. This is because Salmeterol/Fluticasone 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 Salmeterol/Fluticasone:

- $\beta$  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 Salmeterol/Fluticasone, 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.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

### **Driving and using machines**

Salmeterol/Fluticasone is not likely to affect your ability to drive or use machines unless you get side effects such as blurred vision.

### **Salmeterol/Fluticasone contains lactose**

Salmeterol/Fluticasone contains lactose. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions.

### **3. How to use Salmeterol/Fluticasone**

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 Salmeterol/Fluticasone every day until your doctor advises you to stop. Do not use more than the recommended dose. Check with your doctor or pharmacist if you are not sure.
- Do not stop using Salmeterol/Fluticasone or reduce the dose of Salmeterol/Fluticasone without talking to your doctor first.
- Salmeterol/Fluticasone 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**

- Salmeterol/Fluticasone 50 microgram/100 microgram - One inhalation twice a day.
- Salmeterol/Fluticasone 50 microgram/250 microgram - One inhalation twice a day.
- Salmeterol/Fluticasone 50 microgram/500 microgram - One inhalation twice a day.

#### **Children 4 to 12 years of age**

- Salmeterol/Fluticasone 50 microgram/100 microgram - One inhalation twice a day.
- Salmeterol/Fluticasone is not recommended for use in children below 4 years of age.

### **For Chronic Obstructive Pulmonary Disease (COPD)**

#### **Adults**

- Salmeterol/Fluticasone 50 microgram/500 microgram - One inhalation twice a day.

Your symptoms may become well controlled using Salmeterol/Fluticasone 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 **day-time** symptoms.

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

If you are using Salmeterol/Fluticasone 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 use Salmeterol/Fluticasone 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**

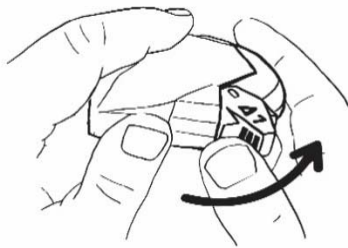
- Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using the Salmeterol/Fluticasone properly or as prescribed may mean that it will not help your asthma or COPD as it should.
- The device holds blisters containing salmeterol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

### **Using your inhaler**

In order to use the inhaler you need to follow the instructions:

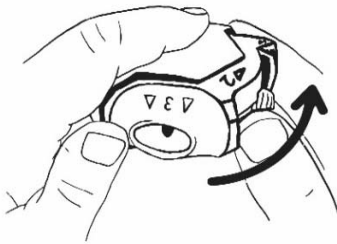
#### **1. Opening:**

- To open your inhaler, 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.



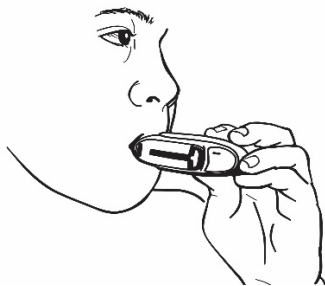
## 2. Load the dose

- 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. You will hear a click. This places a dose of your medicine in the mouthpiece.
- **The inhaler is ready to use.**  
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.**



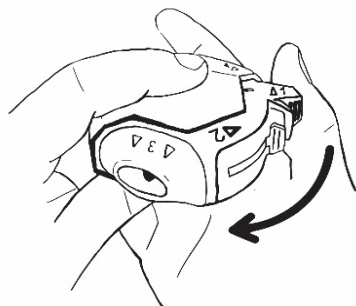
## 3. Inhalation:

- Hold the inhaler away from your mouth, breathe out as far as is comfortable. You need to remember not turn the mouthpiece upside down, it will prevent the medicine waste. **Breathe** out steadily and deeply. Do not breathe into your inhaler.
- Put the mouthpiece to your lips; breathe in steadily and deeply through the inhaler, not through your nose.
- Hold your breath and remove the inhaler from your mouth. Hold your breath for a few seconds or for as long as is comfortable. Breathe out slowly.
- Afterwards rinse your mouth with water and spit it out, and/or brushing your teeth. This may help to stop you getting thrush and becoming hoarse.



## 4. Closing

- To close the inhaler, 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. The outer case protects the inhaler when it is not used.
- Your inhaler is now ready for you to use again.



As with all inhalers, caregivers should ensure that children prescribed Salmeterol/Fluticasone use correct inhalation technique, as described above.

### **Cleaning your inhaler**

Wipe the mouthpiece of Salmeterol/Fluticasone with a dry tissue to clean it.

### **If you use more Salmeterol/Fluticasone 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 taken larger doses for a long period of time, you should talk to your doctor or pharmacist for advice. This is because larger doses of Salmeterol/Fluticasone may reduce the amount of steroid hormones produced by the adrenal gland.

### **If you forget to use Salmeterol/Fluticasone**

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

### **If you stop using Salmeterol/Fluticasone**

It is very important that you use your Salmeterol/Fluticasone every day as directed. **Keep using it until your doctor tells you to stop. Do not stop or suddenly reduce your dose of Salmeterol/Fluticasone.** This could make your breathing worse.

In addition, if you suddenly stop using Salmeterol/Fluticasone or reduce your dose of Salmeterol/Fluticasone 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 Salmeterol/Fluticasone to control your asthma or Chronic Obstructive Pulmonary Disease (COPD).

**Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Salmeterol/Fluticasone.** 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 Salmeterol/Fluticasone, stop using Salmeterol/Fluticasone and tell your doctor straight away.** Allergic reactions to Salmeterol/Fluticasone are uncommon (may affect up to 1 in 100 people).

**Pneumonia (infection of the lung) in COPD patients. (Common side effect, may affect up to 1 in 10 people)**

**Tell your doctor** if you have any of the following while taking Salmeterol/Fluticasone 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 1000 people)**

- **Breathing difficulties or wheezing that get worse straight after taking Salmeterol/Fluticasone.** If this happens **stop using your Salmeterol/Fluticasone inhaler.** Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**
- Salmeterol/Fluticasone 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 Salmeterol/Fluticasone 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 Salmeterol/Fluticasone 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 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, pharmacist or nurse. 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 Salmeterol/Fluticasone**

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 inhaler and carton after EXP. The expiry date refers to the last day of that month.

Store below 25° C.

Store in the original package in order to protect from moisture.

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 Salmeterol/Fluticasone contains**

- The active substances are salmeterol and fluticasone propionate.  
Salmeterol/Fluticasone 50 microgram/100 microgram/dose inhalation powder, pre-dispensed  
Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of in average 49 micrograms of salmeterol (as salmeterol xinafoate) and in average 96 micrograms of fluticasone propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 100 micrograms fluticasone propionate.

Salmeterol/Fluticasone 50 microgram/250 microgram/dose inhalation powder, pre-dispensed  
Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of in average 49 micrograms of salmeterol (as salmeterol xinafoate) and in average 240 micrograms of fluticasone propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 250 micrograms fluticasone propionate.

Salmeterol/Fluticasone 50 microgram/500 microgram/dose inhalation powder, pre-dispensed  
Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of in average 49 micrograms of salmeterol (as salmeterol xinafoate) and in average 484 micrograms of fluticasone propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 500 micrograms fluticasone propionate.

- The other ingredient is lactose monohydrate (which contains milk proteins).

#### **What Salmeterol/Fluticasone looks like and contents of the pack**

- Salmeterol/Fluticasone is a moulded plastic device containing a foil strip with 60 regularly placed blisters.
- Each dose is pre-dispensed.
- The plastic devices are available in cardboard containers, which hold:  
1 x 60, 2 x 60, 3 x 60 or 10 x 60 doses.  
Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

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#### **and Manufacturer**

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