

## Package leaflet: Information for the user

**Salmex 50 microgram /100 microgram /dose inhalation powder, pre-dispensed.**

**Salmex 50 microgram /250 microgram /dose inhalation powder, pre-dispensed.**

**Salmex 50 microgram /500 microgram /dose inhalation powder, pre-dispensed.**

salmeterol/fluticasone propionate

**Read all of this leaflet carefully before you start taking 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 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 Salmex is and what it is used for
2. What you need to know before you use Salmex
3. How to use Salmex
4. Possible side effects
5. How to store Salmex
6. Contents of the pack and other information

### **1. What Salmex is and what it is used for**

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

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

**Salmex helps to stop breathlessness and wheeziness coming on. However Salmex 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 Salmex**

### **Do not take Salmex:**

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

### **Warnings and precautions**

Talk to your doctor before using Salmex if you have:

- Heart disease, including an irregular or fast heart beat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (Salmex 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 Salmex**

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes medicines for asthma or any medicines obtained without a prescription. This is because Salmex 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 Salmex:

- $\beta$  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 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 Salmex, 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**

Salmex is not likely to affect your ability to drive or use machines.

### **Salmex contains lactose**

Salmex contains approximately 13.5 mg of lactose monohydrate in each dose.. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant. The excipient lactose monohydrate contains small amounts of milk proteins, which may cause allergic reactions.

### 3. How to use Salmex

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 Salmex 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 Salmex or reduce the dose of Salmex without talking to your doctor first.
- Salmex should be inhaled through the mouth into the lungs.

#### For asthma

##### Adults and adolescents aged 12 years and over

- Salmex 50 microgram /100 microgram /dose - One inhalation twice a day
- Salmex 50 microgram /250 microgram /dose - One inhalation twice a day
- Salmex 50 microgram /500 microgram /dose - One inhalation twice a day

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

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

##### For adults with Chronic Obstructive Pulmonary Disease (COPD)

- Salmex 50 microgram /500 microgram /dose - One inhalation twice a day

Your symptoms may become well controlled using Salmex 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 Salmex for asthma, your doctor will want to regularly check your symptoms.

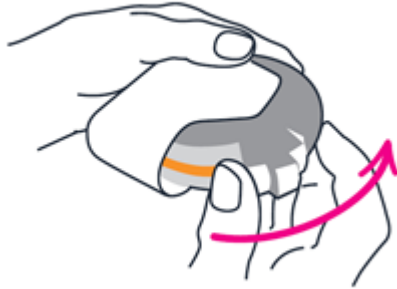
**If your asthma or breathing gets worse tell your doctor straight away.** You may find that you feel more wheezy, your chest feels tight more often or you may need to use more of your fast-acting 'reliever' medicine. If any of these happen, you should continue to take Salmex but do not increase the 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

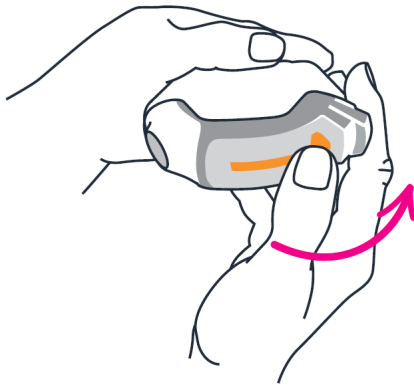
- Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using Salmex properly or as prescribed may mean that it will not help your asthma or COPD as it should.
- Salmex device holds blisters containing salmeterol and fluticasone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

## Using your inhaler

1. To open your Salmex, 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. You will hear a click. This will open a small hole in the mouthpiece. See picture 1.



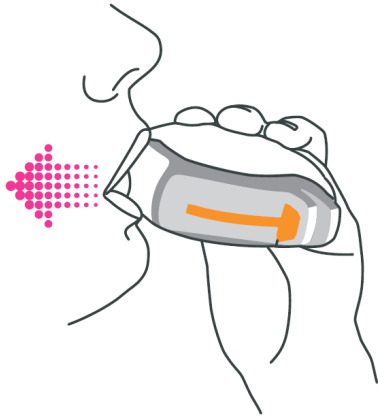
2. Hold your Salmex with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece. See picture 2.



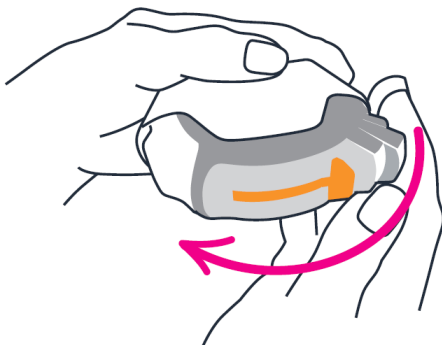
Every time the lever is pulled back a blister is opened inside and the powder made ready for you to inhale. Do not play with the lever as this opens the blisters and wastes medicine.

3. Hold Salmex away from your mouth, breathe out as far as is comfortable. Do not breathe into your Salmex.

- Put the mouthpiece to your lips; breathe in steadily and deeply through Salmex, not through your nose. See picture 3.  
Remove Salmex from your mouth.  
Hold your breath for about 10 seconds or for as long as is comfortable.  
Breathe out slowly.



- 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.
- To close Salmex, 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 picture 4.



Your Salmex is now ready for you to use again.

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

### **Cleaning your inhaler**

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

### **If you use more Salmex 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 Salmex may reduce the amount of steroid hormones produced by the adrenal gland.

### **If you forget to use Salmex**

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 Salmex**

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

In addition, if you suddenly stop taking Salmex or reduce your dose of Salmex 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, nurse or pharmacist.

## **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 Salmex to control your asthma or COPD.

**Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Salmex.** 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 your heart 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 Salmex, stop using Salmex and tell your doctor straight away.** Allergic reactions to Salmex are uncommon (they affect less than 1 person in 100).

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

**Tell your doctor** if you have any of the following while taking Salmex 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 Salmex.** If this happens **stop using your Salmex inhaler.** Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**

- Salmex 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 Salmex 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 Salmex 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 Salmex**

**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.

Store at temperatures below 30°C, in the original package 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 Salmex contains**

- The active ingredients are salmeterol and fluticasone propionate.



- Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 45 micrograms of salmeterol (as salmeterol xinafoate) and 93, 233 or 465 micrograms of fluticasone propionate. This corresponds to a pre-dispensed dose of 50 micrograms of salmeterol (as salmeterol xinafoate) and 100, 250 or 500 micrograms fluticasone propionate.
- The other ingredient is lactose monohydrate (which contains milk proteins).

#### **What Salmex looks like and contents of the pack**

- **Each doses is pre-dispensed**
- **The devices are packed in cartons which hold:**
  - 1 x Salmex containing 60 inhalations
  - 2 x Salmex containing 60 inhalations
  - 3 x Salmex containing 60 inhalations
  - 10 x Salmex containing 60 inhalations

Moulded plastic device containing a foil strip with 60 regularly placed blisters.

#### **Marketing Authorisation Holder**

<To be completed nationally>

#### **Manufacturer**

Celon Pharma S.A.  
ul. Mokra 41A, Kielpin  
05-092 Łomianki

Celon Pharma S.A.  
ul. Marymoncka 15  
05-152 Kazuń Nowy

#### **This leaflet was last revised in**

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