

Package Leaflet: Information for the User

Relanio 50 microgram/250 microgram/dose inhalation powder, pre-dispensed
Relanio 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 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 <Product name> is and what it is used for
2. What you need to know before you use <Product name>
3. How to use <Product name>
4. Possible side effects
5. How to store <Product name>
6. Contents of the pack and other information

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

<Product 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). <Product name> at a dose of 50/ 500 micrograms, reduces the number of flare ups of COPD symptoms.

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

<Product name> helps to stop breathlessness and wheeziness coming on. However, <Product 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 <Product name>

Do not take <Product name>:

If you are allergic to salmeterol, fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before using <Product name> if you have:

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

Other medicines and <Product name>

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 <Product name> 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 <Product 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 <Product 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

<Product name> is not likely to affect your ability to drive or use machines.

<Product name> contains lactose

The amount does not normally cause problems in lactose intolerant people. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions.

3. How to use <Product 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 <Product 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 <Product name> or reduce the dose of <Product name> without talking to your doctor first.
- <Product name> should be inhaled through the mouth into the lungs.
- After use rinse your mouth with water and spit it out.

For adults with asthma

- <Product name> 50 microgram/250 microgram/ dose: One inhalation twice a day.
- <Product name> 50 microgram /500 microgram/dose: One inhalation twice a day.

For adults with Chronic Obstructive Pulmonary Disease (COPD)

- <Product name> 50 microgram /500 microgram/ dose: One inhalation twice a day.

Use in children and adolescents

<Product name> should not be used in children and adolescents.

Your symptoms may become well controlled using <Product 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 <Product 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 <Product 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 (**Elpenhaler®**). They should check how you use it from time to time. Not using the Relanio properly or as prescribed may mean that it will not help your asthma or COPD as it should.

INSTRUCTIONS FOR USE AND HANDLING OF THE ELPENHALER®

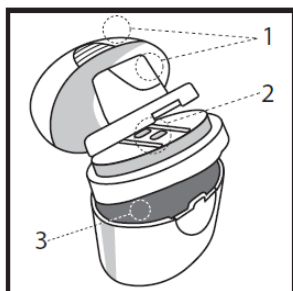
The following are instructions to the patient for the proper inhalation of the two medicines packed in the two blisters of the single dose strips (double-b blister strips), which are stored in the Elpenhaler®.

DESCRIPTION

The Elpenhaler® is a device for inhaling at the same time two medicines which are in the form of powder. The two medicines form in one medicinal combination. Each

medicine is packed separately from the other in one of the two blisters of the specially designed double-blister strip.

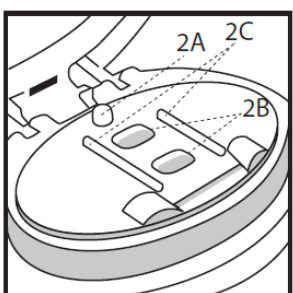
The double-blister strip contains one (1) dose of the medicinal combination.



The Elpenhaler® is comprised of 3 parts:

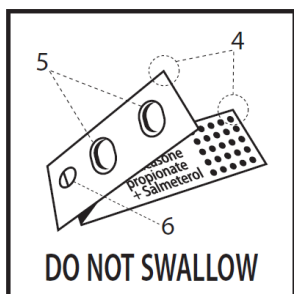
- The mouthpiece and its cap (1).
- The surface (2) on which the double-blister strip is placed (drug supporting surface).
- The storage case (3) which houses the double-blister strips.

The three parts are connected to each other and can be opened separately.



The drug supporting surface contains:

- An attachment point (2A) where the double-blister strip is attached.
- Two cavities (2B) which accommodate the two blisters of the strip.
- Two strip guides (2C) which firmly secure the double-blister strip in the correct position on the drug supporting surface.

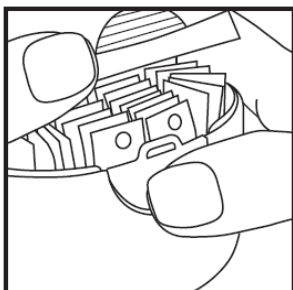


The double-blister strip contains:

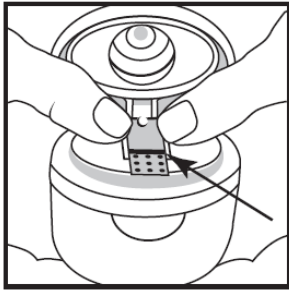
- Two aluminium sheets (4).
- Two blisters (5), one containing salmeterol and the other fluticasone propionate.
- A hole (6).

USE OF THE ELPENHALER®

A. Preparing the device



Open the storage case by pressing as in the figure, take a strip and close the storage case again.



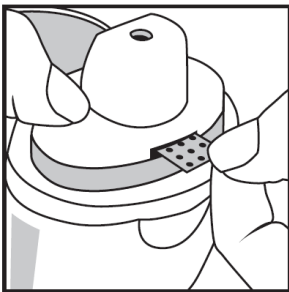
Uncover the mouthpiece completely by applying light pressure on the striped area.

Unlock and push the mouthpiece backwards so as to reveal the drug supporting surface.

Hold the double-blister strip with its shiny surface upwards, so as to see the blue line, as shown by the arrow in the figure. The labeled surface of the strip should face downwards.

Place the hole of the strip on the attachment point of the drug supporting surface. By applying light pressure make sure the strip is securely attached on the attachment point.

The two blisters of the strip will fit in the cavities of the drug supporting surface and the guides will secure the strip in the correct position.

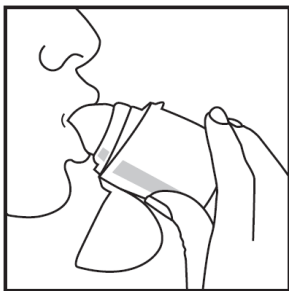


Close the mouthpiece and pull away horizontally the embossed protruding end of the strip to be detached.

The dose is now ready to be inhaled.

B. Inhalation of the dose

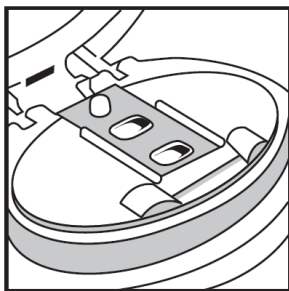
Hold the device away from your mouth. Exhale completely. Be careful not to exhale on the mouthpiece of the device. Bring the Elpenhaler® to your mouth and place your lips tightly around the mouthpiece.



Breathe in slowly and deeply from your mouth (and not from your nose) until your lungs are full.

Hold in your breath approximately 5 seconds or as long as you comfortably can and at the same time remove the device from your mouth.

Exhale and continue to breathe normally.



Open the mouthpiece. You will notice that you have inhaled all the powder and that the blisters of the strip are empty.

Remove the empty strip and proceed to step C.

C. Cleaning the device

Following each use, wipe the mouthpiece and the drug supporting surface with a dry cloth or dry paper tissue. Do not use water to clean the device.
Close the mouthpiece and its cap.

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

If you forget to use <Product 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 <Product name>

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

In addition, if you suddenly stop taking <Product name> or reduce your dose of <Product 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 potassium 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 <Product name> to control your asthma or COPD.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using <Product 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 <Product name>, stop using <Product name> and tell your doctor straight away.** Allergic reactions to <Product name> are uncommon (they 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 <Product 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 <Product name>.** If this happens **stop using <Product name> inhaler.** Use your fast-acting 'reliever' inhaler to help your breathing and **tell your doctor straight away.**
- <Product 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 <Product 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 <Product 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 <Product 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.
- Store 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 <Product name> contains

The active substances are

50 micrograms salmeterol (as salmeterol xinafoate) and 250 micrograms fluticasone propionate.

or

50 micrograms salmeterol (as salmeterol xinafoate) and 500 micrograms fluticasone propionate.

The other ingredient is lactose monohydrate.

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

<Product name> contains salmeterol and fluticasone propionate packed in the two blisters of the single dose foil strips (double-blister strips), which are stored in the inhalation device Elpenhaler®.

The foil protects the powder for inhalation from the effects of the atmosphere.

Each dose is pre-dispensed in one double-blister strip.

Each carton box contains one inhalation device Elpenhaler® with 30 alu-alu double blister strips. 30 doses per pack

Each carton box contains one inhalation device Elpenhaler® with 30 double blister strips and one spare canister with 30 additional double blister strips. 60 doses per pack

Each carton box contains one inhalation device Elpenhaler® with 60 alu-alu double blister strips. 60 doses per pack

Each carton box contains three inhalation devices Elpenhaler® with 60 alu-alu double blister strips each. 180 doses per pack

Marketing Authorisation Holder and Manufacturer

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Greece

This leaflet was last revised in 2019-03-21.

<To be completed nationally.>