

Package Leaflet: Information for the User

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

1. What Flamerio is and what it is used for

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

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

Flamerio helps to stop breathlessness and wheeziness coming on. However Flamerio 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 Flamerio

Do not take Flamerio:

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

Warnings and precautions

Talk to your doctor or pharmacist before using Flamerio if you have:

- Heart disease, including an irregular or fast heartbeat
- Overactive thyroid gland
- High blood pressure
- Diabetes mellitus (Flamerio may increase your blood sugar)
- Low potassium in your blood
- Tuberculosis (TB) now or in the past, or other lung infections.

Other medicines and Flamerio

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 prescription.

Tell your doctor if you are taking the following medicines, before starting to use Flamerio.

- β blockers (such as atenolol, propranolol, sotalol). β blockers are mostly used for high blood pressure or other heart conditions.
- Medicines to treat infections (such as ritonavir, cobicistat, ketoconazole, itraconazole and erythromycin). Some medicines may increase the effects of Flamerio and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat). This can increase your risk of experiencing side effects with Flamerio, including irregular heart beats, or may make side effects worse.
- 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 planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

Flamerio 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 Flamerio

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

For adults with asthma

- Flamerio 50 microgram/250 microgram/ dose: One inhalation twice a day.
- Flamerio 50 microgram /500 microgram/dose: One inhalation twice a day.

For adults with Chronic Obstructive Pulmonary Disease (COPD)

Flamerio 50 microgram /500 microgram/ dose: One inhalation twice a day.

Use in children and adolescents

Flamerio should not be used in children and adolescents.

Your symptoms may become well controlled using Flamerio 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 Flamerio 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 Flamerio 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

Flamerio properly or as prescribed may mean that it will not help your asthma or COPD as it should.

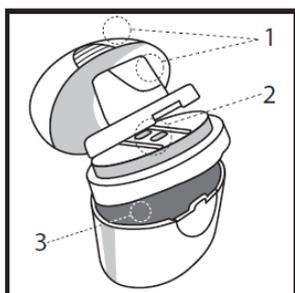
INSTRUCTIONS FOR USE AND HANDLING OF THE ELPENHALER

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-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.

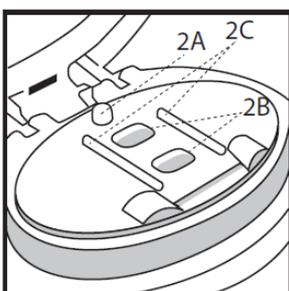
The double-blister strip contains one (1) dose of the medicinal combination.



The Elpenhaler is comprised of 3 parts:

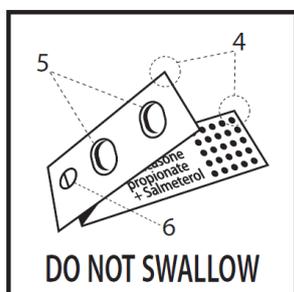
- The mouthpiece and its cap (1).
- The surface (2) on which the double-blister strip is placed (drug supporting surface).
- The storage case (3) which houses the double-blister strips.

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.

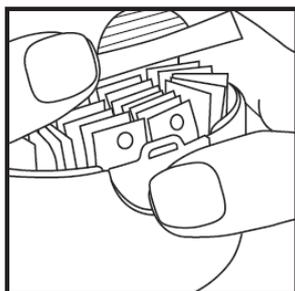


The double-blister strip contains:

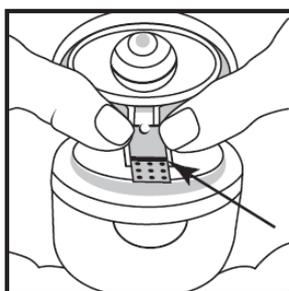
- Two aluminium sheets (4).
- Two blisters (5), one containing salmeterol and the other fluticasone propionate.
- A hole (6).

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.



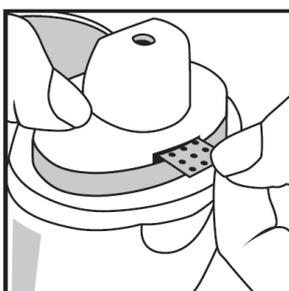
Uncover the mouthpiece completely by applying light pressure on the stripped area.

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 supporting surface and the guides will secure the strip in the correct position.

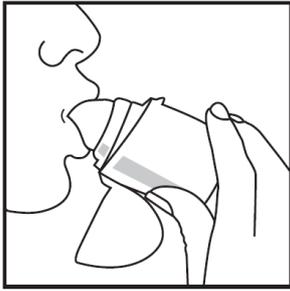


Close the mouthpiece and pull away horizontally the embossed protruding end of the strip to be detached.

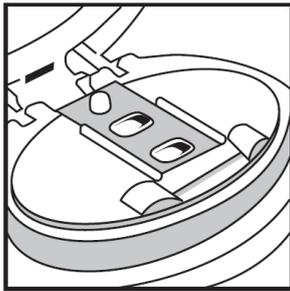
The dose is now ready to be inhaled.

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 Flamerio 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 Flamerio may reduce the amount of steroid hormones produced by the adrenal gland.

If you forget to use Flamerio

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 Flamerio

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

In addition, if you suddenly stop taking Flamerio or reduce your dose of Flamerio 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 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 Flamerio to control your asthma or COPD.

Allergic reactions: you may notice your breathing suddenly gets worse immediately after using Flamerio. 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 these effects or if they happen suddenly after using Flamerio, tell your doctor straight away.** Allergic reactions to Flamerio 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 Flamerio 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 has 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 antifungal 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 amount of potassium in the blood (you may get an uneven heartbeat, 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 heartbeat (tachycardia).
- Feeling shaky (tremor) and fast or uneven heartbeat (palpitations) – these are usually harmless and get less as treatment continues
- Feeling worried (this effect mainly occurs in children)
- Disturbed sleep.
- Chest pain
- Allergic skin rash

Rare: *may affect up to 1 in 1,000 people*

- **Breathing difficulties or wheezing that get worse straight after taking Flamerio.** If this happens **stop using Flamerio.** Use your fast-acting ‘reliever’ inhaler to help your breathing and **tell your doctor straight away.**
- Flamerio 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 Flamerio to control your asthma.

- Behavioural changes, such as being unusually active and irritable (these effects mainly occur in children).
- Uneven heartbeat or heart gives an extra beat (arrhythmias). Tell your doctor, but do not stop taking Flamerio 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 and or aggression. These effects are more likely to occur in children.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly at HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flamerio

Keep this medicine out of the sight and reach of children.

Store below 25 °C.

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 throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines if you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Flamerio contains

The active substances are salmeterol xinafoate and fluticasone propionate. Each pre-dispensed dose of Flamerio contains:

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

or

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

The other ingredient is lactose monohydrate.

What Flamerio looks like and contents of the pack

Flamerio contains salmeterol and fluticasone propionate packed in the 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 60 double blister strips. Pack size: 60 doses

Each carton box contains one inhalation device Elpenhaler with 30 alu-alu double blister strips and one spare storage compartment with 30 additional alu-alu double blister strips. Pack size: 60 doses.

Each carton box contains one inhalation device Elpenhaler with 30 alu-alu double blister strips. Pack size: 30 doses (sample pack).

Each carton box contains three inhalation devices Elpenhaler with 60 alu-alu double blister strips each. Pack size: 180 doses.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

ELPEN Pharmaceutical Co. Inc
95, Marathonos Ave., GR-19009 Pikermi, Attica
Greece

Manufacturer

ELPEN Pharmaceutical Co.Inc 95, Marathonos Ave., GR-19009 Pikermi, Attica
Greece

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Salmeson 50 Mikrogramm /250 Mikrogramm/Dosis, 50 Mikrogramm /500 Mikrogramm/Dosis Einzeldosiertes Pulver zur Inhalation
Belgium	Flusalio 50microgram/250microgram/dose, 50microgram/500microgram/dose Poudre pour inhalation en récipient unidose
Denmark	Flusaterol
Ireland	Flamerio 50microgram/250microgram/dose, 50microgram/500microgram/dose inhalation powder, pre-dispensed
The Netherlands	Salmeterol/Fluticasonpropionaat Elpen 50microgram/250microgram/ dosis, 50microgram/500microgram/dosis Inhalatiepoeder, voorverdeeld

Sweden Flusaterol 50microgram/250microgram/dos,
50microgram/500microgram/dos
Inhalationspulver, avdelad dos

This leaflet was last revised in 2018