Package leaflet: Information for the patient

Fluticasone Elpen 250 microgram/dose Inhalation powder, pre-dispensed
Fluticasone Elpen 500 microgram/dose Inhalation powder, pre-dispensed
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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What 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> is a cortisone preparation that counteracts inflammation and allergy directly in the lungs. Reducing inflammation can prevent asthma attacks.

<Product name> is used as a regular treatment for asthma and COPD (Chronic Obstructive Pulmonary Disease) together with a long-acting bronchodilator. The full effect is first observed after several days of regular treatment. <Product name> does not provide rapid relief in the event of acute asthma attacks. If such event occur, a quick and short-acting bronchodilator medicine should be used. If the treatment does not give the desired effect, consult a doctor.

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

Do not use <Product name>

- if you are allergic to fluticasone propionate or any of the other ingredients in this medicine (specified in section 6). Lactose monohydrate may contain lactoprotein.

Warnings and precautions
Talk to your doctor, nurse or pharmacist before using <Product name>.

<Product name> is not intended for the treatment of acute asthma symptoms. You should use a fast acting “reliever” inhaler, such as a short-acting bronchodilator, for acute asthma attacks.

Immediately after taking <Product name>, a paradoxical bronchospasm (respiratory cramp) with increased wheezing may occur. If this does occur, you should immediately inhale a fast-acting bronchodilator. Stop taking <Product name> and contact your doctor.

If you have previously been treated with cortisone tablets, you must carefully follow the doctor's dosage instructions when switching to <Product name>. In the event of such a transition, your previous allergy symptoms, such as sniffing and eczema, may return. You may also experience fatigue, headache, muscular and joint aches, and sometimes nausea and vomiting. This is because the total amount of cortisone in the body is reduced as the illness in the lungs is treated locally. The

systems will abate after a certain amount of time. **If the symptoms escalate, do not change the dose without contacting a doctor.**

In the event of acute deterioration, episodic stress events and surgical procedures, treatment may need to be supplemented with cortisone in tablet form. Contact your doctor for written information on how your cortisone treatment will proceed in the event of the aforementioned situations.

Treatment with <Product name> must not be discontinued abruptly, as this may risk aggravating the symptoms. Your doctor will decide how quickly the dose can be reduced.

Tell your doctor if you suffer from pulmonary tuberculosis before you start <Product name> treatment.

In very rare cases, <Product name> may affect blood sugar levels. If you suffer from diabetes, consult your doctor before using <Product name>.

Using high doses of <Product name> over a long period may cause the cortisone to affect the entire body. You may experience symptoms such as weight gain with altered fat distribution (abdomen, neck, face), thin and fragile skin, increased body hair, decreased bone density, high blood pressure (Cushing's syndrome). Growth inhibition may be seen in children and adolescents. If any of these symptoms are observed, consult your doctor.

The long-term growth of children treated with <Product name> should be checked regularly.

Contact a doctor if you experience blurred vision or other visual disorders.

Other medicines and <Product name>
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription.

Certain other medicines may increase the effect of <Product name>, and your doctor may want to monitor you carefully if you are taking these medicines (e.g. certain medicines for HIV: ritonavir, cobicistat, or antifungal medicines: ketoconazole, itraconazole).

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 taking this medicine.
There is limited experience of use during pregnancy. You should, therefore, consult a doctor **before** using <Product name> during pregnancy.

It is unknown whether fluticasone propionate passes through human milk. For this reason, consult a doctor **before** using while breastfeeding.

Driving and using machines
<Product name> is not likely to affect you being able to drive or use any tools or machines, unless side effect such as blurred vision occurs.

<Product name> contains lactose

Each dose of <Product name> 250 microgram & 500 microgram contains approximately 14 mg of 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 <Product name>

Always use this medicine exactly as your doctor or pharmacist has told you. The dose is determined

by the doctor, who will adapt it specifically for you. Do not exceed the dosage. Check with your doctor, nurse or pharmacist if you are not sure.

<Product name> is generally inhaled in the morning and evening. In order to achieve full effect, <Product name> should be used regularly. **The mouth should be rinsed with water after each inhalation.** See the user instructions for more information.

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 <Product name> properly or as prescribed may mean that it will not help your asthma as it should.
- The Elpenhaler device holds a blister on each strip containing <Product name> as a powder.

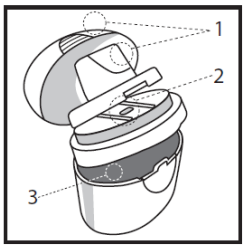
Do not use your inhaler more often than the doctor told you to. Tell your doctor if your medicine does not seem to be working as well as usual, as your chest problem may be getting worse and you may need a different medicine.

INSTRUCTIONS FOR USE OF THE ELPENHALER

Elpenhaler is a device for the intake of powder for inhalation in doses. Each dose is stored in the blister of a specially designed single dose blister strip.

Elpenhaler device is comprised of 3 parts:

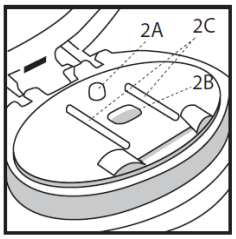
- The mouthpiece and its cap **(1)**.
- The surface **(2)** on which the blister strip is placed (drug supporting surface).
- The storage case **(3)** which houses the blister strips.

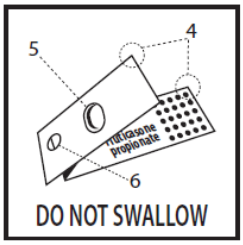


The three parts are connected to each other and can be opened separately.

The drug supporting surface contains:

- An attachment point **(2A)** where the blister strip is attached.
- A cavity **(2B)** which accommodates the blister of the strip.
- Two strip guides **(2C)** which firmly secure the blister strip in the correct position on the drug supporting surface.



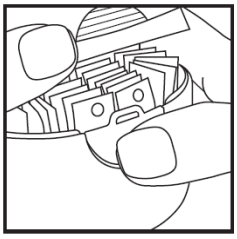


The blister strip consists of:
- Two aluminium sheets **(4)**.
- A blister **(5)**, containing the medicine.
- A hole **(6)**.

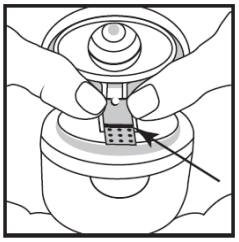
USE OF THE ELPENHALER

A. Preparing the device

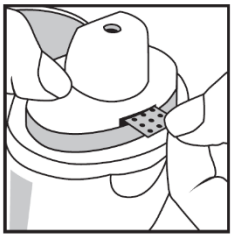
- Open the storage case by pressing as in the figure, take a strip and close the storage case again.



- 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 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 that the strip is securely attached on the attachment point.
- The blister of the strip will fit in the cavity 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.

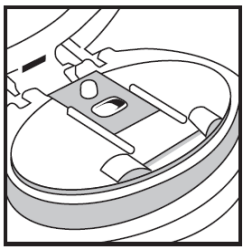


B. Inhalation of the dose

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

- Breathe in slowly and deeply through your mouth (and not through 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 blister of the strip is 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 take more <Product name> than you should
It is important that you take the dose as indicated on the packaging label, or as your doctor has directed. Do not increase or decrease the dose without consulting a doctor.

If you forget to take <Product name>
Continue treatment as usual if you have forgotten to take a dose. Do not take a double dose to make up for a forgotten dose.

If you stop using <Product name>
Treatment with <Product name> must not be discontinued abruptly, as this may risk aggravating the symptoms. Your doctor will decide how quickly the dose can be reduced.

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.

Contact a doctor immediately if you experience any of the following symptoms (signs of an allergic/anaphylactic reaction):
swelling of the face, mouth and throat, spasms in the trachea (windpipe), shortness of breath. This is a very rare adverse reaction.

Inform your doctor if you experience any of the following symptoms while taking <Product name>, as they may be symptoms of pneumonia:
- fever or chills
- increased mucus production, altered colour of the mucus

- increased coughing or increased breathing difficulties.

COPD patients have reported pneumonia as a common adverse reaction (may affect up to 1 in 10 people).

Other possible side effects

Very common (may affect more than 1 in 10 people):

- fungal infection ("thrush", Candida) in the oral cavity, larynx and pharynx. The risk of infection can be decreased by rinsing the mouth with water after each inhalation.

Common (may affect up to 1 in 10 people):

- bruising
- throat irritation and hoarseness

Less common side effects (may affect up to 1 in 100 people):

- hypersensitivity reactions in the form of skin rashes.

Rare side effects (may affect up to 1 in 1000 people):

- fungal infection in the oesophagus.

Very rare side effects (may affect up to 1 in 10,000 people):

- inhalation treatment may cause cramps in the trachea due to uncertain mechanisms
- sleeping issues, apprehension, restlessness, anxiety (these adverse reactions are more likely to occur in children)
- Cushing-like symptoms (moon face, abdominal obesity)
- reduced cortisone formation in adrenal glands
- reduced bone density
- glaucoma (green star), cataracts (grey star)
- delayed long-term growth in children has been observed in very rare cases when cortisone has been administered in high doses over a long period
- Elevated blood sugar levels have been reported in very rare cases.

Have been reported (occurs for an unknown number of people):

- depression, feeling irritable and/or very upset. These adverse reactions are more likely to occur in children.
- nosebleeds
- 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 <Product name>

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use this medicine after the expiry date which is stated on the 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 you no longer use. These measures will help protect the environment. As medicine residues may remain in the empty packages, do not throw them into the trash. The empty packages should also be returned to the pharmacy.

6. Contents of the pack and other information

What <Product name> contains

The active substance is fluticasone propionate

Each dose of <Product Name> 250 microgram contains 250 microgram of fluticasone propionate
Each dose of <Product Name> 500 microgram contains 500 microgram of fluticasone propionate

The other ingredient is lactose.

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

<Product name> contains fluticasone propionate packed in blisters, which are stored in the inhaler Elpenhaler.

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

A white plastic device containing alu-alu blisters, is packed in a carton box together with the instruction leaflet.

Each carton box contains:

- 30 doses: one inhaler Elpenhaler with 30 alu-alu blisters.

Or

- 60 doses: one inhaler Elpenhaler with 60 alu-alu blisters.

Or

- 120 doses: two inhalers Elpenhaler with 60 alu-alu blisters.

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:
<To be completed nationally>

This leaflet was last revised in 2019-07-15.