

Flixotide EVOHALER

Fluticasone propionate

Name of the medicinal product

FLIXOTIDE EVOHALER 50 micrograms/dose
FLIXOTIDE EVOHALER 125 micrograms/dose
FLIXOTIDE EVOHALER 250 micrograms/dose

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 FLIXOTIDE EVOHALER is and what it is used for
2. What you need to know before you use FLIXOTIDE EVOHALER
3. How to use FLIXOTIDE EVOHALER
4. What are the possible side effects
5. How to store FLIXOTIDE EVOHALER
6. Contents of the pack and other information.

1. What FLIXOTIDE EVOHALER is and what it is used for

Pharmacotherapeutic class: Glucocorticoid for inhalation use - ATC code: R03BA05.

This medicinal product is a corticoid (*derived from cortisone*) that is only administered by oral inhalation (*by inhaling it*).

It's an anti-inflammatory medicine recommended in regular doses for the ongoing treatment of asthma.

You should not discontinue this treatment without medical advice, even if your symptoms very clearly improve.

**Warning: this medicine is not a bronchodilator.
It is not a treatment for asthma attacks.**

It does not provide immediate relief. In particular, it has no registered effect on asthma attacks.

Its effectiveness only manifests after several days and depends on strictly following the posology (*doses and number of daily administrations*) prescribed by your doctor, which is adapted to you personally.

2. What you need to know before you use FLIXOTIDE EVOHALER

Do not use FLIXOTIDE EVOHALER

- if you are allergic to fluticasone propionate or any of the other ingredients of this medicine listed in section 6.

Do not continue using this medicine:

- if an increase in breathing difficulty occurs after inhalation of this product, but contact your doctor (see section 4: Possible side effects).

Ask your doctor or pharmacist for advice if you are not sure.

Warnings and precautions

Talk to your doctor or pharmacist before using FLIXOTIDE EVOHALER.

Your doctor will monitor your treatment more closely if you have medical problems such as:

- diabetes (Flixotide can increase the level of glucose in your blood),
- tuberculosis currently progressing or that occurred in the past.

Special warnings

If you have an asthma attack or breathing difficulty, do not use this medicine but use an inhaled fast- and short-acting beta-2 adrenergic receptor agonist (*medicine that increases the size of the bronchi*) that your doctor will have prescribed for you for this purpose.

The relief usually obtained should then be observed rapidly.

If it does not, consult a doctor immediately.

If you experience an increase in asthma attacks or episodes of breathing difficulty are occurring more often, the usually effective daily doses of this medicine are becoming insufficient. An aggravation of the disease should then be feared. If that happens, **talk to your doctor straight away to have your treatment reassessed.**

Precautions

This active inhalation product must reach the ends of the small bronchi in order to act effectively. If the respiratory tracts are congested (by abundant mucus) or in case of infection, its effectiveness may be reduced. You should **contact your doctor straight away so that he can institute suitable treatment.**

Talk to your doctor or pharmacist before using FLIXOTIDE EVOHALER.

Children

Not applicable.

Other medicines and FLIXOTIDE EVOHALER

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you are taking:

- some ketoconazole-based medicines (*medicines that treat fungal infection*)
- some medicines like ritonavir or cobicistat (*medicines used to treat HIV infection*), since they can increase the effects of Flixotide and it is possible that your doctor will wish to monitor you closely if you are taking these medicines.

FLIXOTIDE EVOHALER with food and drink

Not applicable.

Pregnancy and lactation

This medicine should only be used during pregnancy on the advice of your doctor.

If you discover that you are pregnant during treatment, contact your doctor, as only he can judge the most suitable treatment for you.

Ask your doctor or pharmacist for advice before taking any medicine.

Sports

Warning, this medicine contains active ingredients capable of inducing a positive reaction in doping tests.

Driving and using machines

Flixotide does not affect the ability to drive or operate machinery.

FLIXOTIDE EVOHALER contains

Not applicable.

3. How to use FLIXOTIDE EVOHALER

Dose and frequency of administration

The dosage is strictly individual and will be adapted by your doctor to the severity of your asthma.

The daily dose is generally divided into two doses per day.

As a guideline, the daily dosage of this medicine is:

For FLIXOTIDE EVOHALER 50 micrograms/dose:

- **Adults:** 4 to 40 inhalations per day divided into 2 doses per day. There are presentations of higher doses better adapted for the administration of higher posologies. They must be used in this case.

- **In children over 4 years of age:** 2 to 8 inhalations per day divided into 2 doses per day. In children over 4 years of age, except for severe cases, after several days (or weeks) of treatment when symptoms have regressed and asthma is stabilized, your doctor may prescribe this medicine in one daily dose.

- **In children from 1 to 4 years of age:** 2 to 4 inhalations per day divided into 2 doses per day.

For FLIXOTIDE EVOHALER 125 micrograms/dose:

- **Adults:** 2 to 16 inhalations per day divided into 2 doses per day.

- **In children over 4 years of age:** 2 inhalations per day divided into 2 doses per day. In children over 4 years of age, except for severe cases, after several days (or weeks) of treatment when symptoms have regressed and asthma is stabilized, your doctor may prescribe this medicine in one daily dose.

For FLIXOTIDE EVOHALER 250 micrograms/dose:

- **Adults:** 2 to 8 inhalations per day divided into 2 doses per day.

The doses must be spread out at regular intervals.

In all cases, follow your doctor's instructions strictly. Do not increase or decrease the dose without consulting your doctor.

In case attacks or episodes of breathing difficulty reappear or become more frequent, the dose and frequency of administration will be increased. Quickly ask for your doctor's advice so that he can adjust the posology for you.

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you feel that the effect of this medicine is too weak or too strong, tell your doctor or pharmacist.

Method of administration:

This medicine is taken by oral inhalation only (*by inhaling it*) through a distributor with a mouth piece (*inhalation use*).

During inhalation, it is preferable to remain seated or standing.

The effectiveness of this medicine partly depends on your using the inhaler correctly. Read the instructions for using the inhaler carefully. If necessary, do not hesitate to ask your doctor or pharmacist to explain things to you in detail.

Verification of the device functioning:

When using the inhaler for the first time or if you have not used it for one week or more, check that it is working properly.

- remove the cover from the mouthpiece by pressing on each side and shake the inhaler well.

- press on the canister to release two puffs of the product into the air.

Use of the device:

After having removed the cover from the mouthpiece by pressing on each side, the patient should:

- verify the absence of foreign bodies inside and outside of the inhaler, including in the mouthpiece.
- shake the inhaler well to ensure that any foreign bodies are removed and that the contents of the inhaler are evenly mixed.(fig 1)

- empty your lungs by breathing out deeply, (fig.2)
- place the mouthpiece in the mouth, with the bottom of the metal canister facing up (fig. 3)
- start breathing in and press down on the metal canister, breathing in slowly and deeply all the time (fig. 3),
- remove the mouthpiece from your mouth and hold your breath for at least 10 seconds (fig.4),
- replace the cover on the mouthpiece and press firmly to return it to its position,
- rinse your mouth after inhalation of the product,
- the mouthpiece should be cleaned after use for hygienic purposes.



Practise your inhalation technique in front of a mirror:

If a large amount of product comes out of your nose or mouth, the following points should be checked: either you started to press the metal canister before starting or after finishing to breathe in, or you are not breathing in deeply enough.

If it is difficult to use the inhaler (in particular, in young children), your doctor may advise you to use a spacer (*container placed on the mouthpiece that allows you to inhale the medicine more easily*).

Cleaning the device:

For proper functioning, the inhaler should be cleaned at least once a week.

To clean the device:

Remove the cover from the mouthpiece.

Do not separate the canister from the plastic actuator at any time.

Wipe the inside and outside of the mouthpiece and plastic actuator with a tissue or clean and dry cloth.

Replace the cover on the mouthpiece until you hear a "click" indicating that it is appropriately attached. If you do not hear the click, turn the cover in the other direction and try again without forcing.

Do not immerse the metal canister in water.

Duration of treatment

Follow your doctor's prescription. Do not increase the dose your doctor prescribed to you. Check with your doctor or pharmacist if you are not sure.

The treatment of asthma require daily effort from you.

This medicine should be taken regularly and for as long as your doctor has told you.

If you use more For FLIXOTIDE EVOHALER than you should:

Not applicable.

If you forget to take FLIXOTIDE EVOHALER

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking FLIXOTIDE EVOHALER

Not applicable.

4. What are the possible side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience persistent mouth or throat discomfort, inform your doctor. Do not change or stop treatment without consulting him.

The following may be observed:

- **Very common:** Candidiasis of the mouth or throat (infection due to a fungus). It rarely requires discontinuing this treatment, but it may require specific treatment be started. You can avoid these effects by rinsing your mouth after inhaling the product.

- **Common:** hoarseness; contusions (bruises on the skin).

Some people may also experience throat discomfort and difficulty swallowing. You can avoid these effects by rinsing your mouth immediately after inhaling the product.

- **Uncommon:** allergic reactions with rashes (on the skin).

- **Rare:** Candidiasis of the oesophagus (infection due to a fungus).

- **Very rare:**

- allergic reactions with swelling (of the face, lips or throat) and/or difficulty breathing, cases of widespread allergy; anxiety, difficulty sleeping, agitation, nervousness, and behaviour disorders such as hyperexcitation and irritability (these effects occur mainly in children); increase in glycaemia (level of sugar in your blood).

If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetes treatment may be required.

- possibility of glaucoma (eye disorder associated with an increase in pressure inside the eye) or cataract (opacification of the pigmentation of the eye generally causing a visual disorder). If you have blurred vision or eye pain, check with your doctor.

- **Undetermined frequency:** depression, aggressiveness (mainly in children), epistaxis (nosebleed).

In very rare cases, this treatment may affect the normal production of steroid hormones in the body. This happens more specifically during long-term treatment at high doses. In very rare cases, slowed growth in children and teenagers may be observed. Excess corticoids in the body may cause the following effects: round face (in Cushing's syndrome), bone thinning, eye disorders such as glaucoma (*pain*) or a cataract (*blurred vision*).

As with other inhaled products, increased breathing difficulty may rarely occur (e.g.: bronchospasm = contraction of the bronchi) after inhalation of this product. In this case, do not take another dose; contact your doctor.

Reporting of side effects

To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via gulf.safety@gsk.com

5. How to store FLIXOTIDE EVOHALER

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 box and canister. The expiry date refers to the last day of that month.

Immediately after use, replace the cover on the mouthpiece and press it firmly into position. Do not force the cover on.

Store below 30 °C.

Pressurized container:

- **Do not expose to excessive heat** (to a temperature greater than 50 °C, or to the sun)

- **Do not pierce.**

- **Do not incinerate, even empty.**

Do not use this medicine if you notice signs of deterioration.

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 FLIXOTIDE EVOHALER contains

The active substance is fluticasone propionate

One dose contains 50, 125 or 250 micrograms of fluticasone propionate

The other ingredients are:

Propellant gas: norflurane (tetrafluoroethane or HFA 134a)

What FLIXOTIDE EVOHALER looks like and contents of the pack

This medicine consists of a suspension for inhalation in a pressurised canister containing 60 or 120 doses.

Marketing Authorisation Holder

Laboratoire GLAXOSMITHKLINE

23, rue François Jacob, 92500 Rueil-Malmaison, France

Manufacturer

GLAXO WELLCOME PRODUCTION*

Zone Industrielle n°2, 23, rue Lavoisier, 27000 EVREUX, France

*Member of the GSK group of companies

This leaflet was last revised on:

21/09/2017

Other

For full prescribing information, please contact GlaxoSmithKline, P.O.Box 50199 Dubai, United Arab Emirates.

Trademarks are owned by or licensed to the GSK group of companies

© 2018 GSK group of companies or its licensor

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.