

Package Leaflet: Information for the user

**Flixotide® Evohaler® 125 micrograms per metered dose
Pressurised Inhalation, Suspension
Flixotide® Evohaler® 250 micrograms per metered dose
Pressurised Inhalation, Suspension**

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, nurse 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 the leaflet. See section 4.

What is in this leaflet:

1. What Flixotide is and what it is used for
2. What you need to know before you use Flixotide
3. How to use Flixotide
4. Possible side effects
5. How to store Flixotide
6. Contents of the pack and further information

1. What Flixotide is and what it is used for

Flixotide contains fluticasone propionate which belongs to a group of medicines called corticosteroids (often just called steroids). Flixotide works by reducing swelling and irritation in the lungs. It has an anti-inflammatory action. Only a very small dose is needed as it is inhaled straight to the lungs.

Flixotide helps to prevent asthma attacks in people who need regular treatment. This is why it is sometimes called a 'preventer'. It needs to be used regularly, every day.

Flixotide will not help treat sudden asthma attacks where you feel breathless.

- A different medicine is used for treating sudden attacks (called a 'reliever').
- If you have more than one medicine, be careful not to confuse them.

Flixotide also reduces symptoms in chronic obstructive pulmonary disease (COPD) when used in combination with other medicines called long acting bronchodilators. Only the 250 mcg strength Flixotide Evohaler is suitable for the treatment of COPD.

2. What you need to know before you use Flixotide

Do not use Flixotide:

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

Warnings and Precautions

Talk to your doctor, nurse or pharmacist before taking Flixotide if:

- you have ever been treated for tuberculosis (TB).
- you have ever had thrush in your mouth
- you are using Flixotide at the same time as taking steroid tablets. Also if you have just finished taking steroid tablets. In both cases, you should carry a steroid warning card until your doctor tells you not to carry one.
- you have been diagnosed with diabetes mellitus (Flixotide may increase your blood sugar).

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before using Flixotide.

If you find your reliever medicine is not working as well as before, or you need to take more than usual, go and see your doctor.

If your breathing suddenly gets worse, this can be life-threatening so seek medical advice urgently.

If your breathing or wheezing gets worse straight after using Flixotide Evohaler, **stop using it and tell your doctor immediately.**

Contact your doctor if you experience blurred vision or other visual disturbances, which may be caused by cataract or glaucoma.

Other medicines and Flixotide

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go into hospital.

In particular tell your doctor or pharmacist if you are taking any of the following:

- a type of antiviral medicine known as a 'protease inhibitor' (such as ritonavir) or cobicistat containing products which may increase the effects of fluticasone propionate. Your doctor may wish to monitor you carefully if you are taking these medicines.
- medicines used to treat fungal infections (such as ketoconazole).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Flixotide.

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.

3. How to use Flixotide

Flixotide Evohaler comes in three different strengths. Your doctor will have decided which strength you need. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You should not increase or decrease your dose without seeking medical advice.

Using this medicine

The medicine in Flixotide should be inhaled using a special kind of inhaler called an Evohaler.

- Make sure that you have one and can use it properly
- Instructions on how to use the inhaler are given as a step-by-step guide below.

- Some people find it difficult to release a puff of medicine just after they start to breathe in. A spacer device helps to overcome this problem. Your doctor, nurse or pharmacist will be able to advise you about this.
- **It takes a few days for this medicine to work and it is very important that you use it regularly.**

Adults and Children over 16 years of age

Mild asthma

- The usual starting dose is up to 250 micrograms twice a day.

Moderate asthma

- The usual starting dose is 250 to 500 micrograms twice a day.

Severe asthma

- The usual starting dose is 500 to 1000 micrograms twice a day.

Chronic Obstructive Pulmonary Disease (COPD)

Adult dose

- 500 micrograms twice daily.

For the treatment of COPD Flixotide is taken with another medicine called a long acting bronchodilator.

Only the 250 mcg strength Flixotide Evohaler is suitable for the treatment of COPD.

It may take a few days to a few months for this medicine to work and it is very important that you use it regularly every day. Do not stop treatment, even if you feel better, unless your doctor tells you.

Flixotide Evohaler 125 and 250 micrograms are not recommended for children below 16 years of age.

It is recommended that children being treated with steroids, including Flixotide Evohaler have their height checked regularly by their doctor.

Your doctor may give you a Flixotide 250 microgram Evohaler if your dose is increased.

If you are using high doses of an inhaled steroid for a long time you may sometimes need extra steroids for example during stressful circumstances such as a road traffic accident or before an operation. Your doctor may decide to give you extra steroid medicines during this time.

Patients, who have been on high doses of steroids, including Flixotide Evohaler for a long time, must not stop taking their medicine suddenly without talking to their doctor. Suddenly stopping treatment can make you feel unwell and may cause symptoms such as vomiting, drowsiness, nausea, headache, tiredness, loss of appetite, low blood sugar level and convulsions.

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 Flixotide Evohaler properly or as prescribed, may mean that the medicine will not help your asthma as it should.

The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.

Testing your inhaler

1. When using the inhaler for the first time or if you have not used it for a week or more, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.
2. To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release two puffs into the air.



Using your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

1. Stand or sit upright when using your inhaler.
2. Remove the mouthpiece cover. Check inside and outside to make sure that the mouthpiece is clean and free of objects.
3. Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.



4. Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable. Do not breathe in again yet.



5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.



6. Start breathing in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply.



7. Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.



8. If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.

9. Afterwards, rinse your mouth with water and spit it out.

10. After use replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

Practice in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.

Some people find it difficult to release a puff of medicine just after they start to breathe in. You may find that a spacer device helps to overcome this problem – speak to your doctor if you think you might need one of these.

Children and other people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece. If this does not help, a special device may make it easier. Your doctor, nurse or pharmacist will be able to advise you.

Cleaning your Evohaler

To stop your inhaler blocking, it is important to clean it at least once a week.

To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the canister from the plastic casing.
- Wipe the inside and the outside of the mouthpiece with a dry cloth or tissue.
- Replace the mouthpiece cover.

Do not put the metal canister in water.

If you use more Flixotide than you should

If you use more than you should, **talk to your doctor as soon as possible.**

If you forget to use Flixotide

- Take the next dose when it is due.
- Do not take a double dose to make up for the forgotten dose.

If you stop using Flixotide

- **Do not stop treatment** even if you feel better unless told to do so by your doctor.

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

4. Possible side effects

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

If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straight away. You may need urgent medical treatment.

- allergic reactions (may affect up to 1 in 100 people) – the signs include skin rashes, redness, itching or wheals like nettle rash or hives
- severe allergic reactions (may affect up to 1 in 10,000 people) – the signs include swelling of your face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed and collapse
- your breathing or wheezing gets worse straight after using your inhaler.

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

Tell your doctor if you have any of the following while taking Flixotide - 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 include:

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

- thrush in the mouth and throat

Common (may affect up to 1 in 10 people)

- hoarseness of voice
- bruising

Problems with your mouth and throat can be reduced by doing certain things straight after inhaling your dose. These are brushing your teeth, rinsing your mouth or gargling with water and spitting it out. Tell your doctor if you have these problems with your mouth or throat, but do not stop treatment unless you are told to.

Rare (may affect up to 1 in 1000 people)

- thrush (candidiasis) in the oesophagus

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

- sleeping problems or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children.
- level of sugar (glucose) in your blood may be increased.
- the way steroids are produced by your body may be affected when using Flixotide (adrenal suppression). This is more likely to happen if you use high doses for a long period of time (e.g. 400 micrograms daily in children). This can cause:
 - young people to grow more slowly.
 - something called 'Cushing's syndrome'. This happens when you have too much steroid in your body and it can cause thinning of your bones and eye problems (such as cataracts and glaucoma which is high pressure in the eye).

Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

Frequency not known, but may also occur

- depression or aggression. These effects are more likely to occur in children.
- Nosebleeds.
- blurred vision (that may be due to cataract or glaucoma).

Talk to your doctor as soon as possible if:

- after 7 days of using Flixotide your shortness of breath or wheezing does not get better, or gets worse.

- you or your child is on high doses of inhaled steroid and become unwell with vague symptoms such as tummy ache, sickness, diarrhoea, headache or drowsiness. This can happen during an infection such as a viral infection or stomach upset. It is important that your steroid is not stopped suddenly as this could make your asthma worse and could also cause problems with the body's hormones.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flixotide

- Keep this medicine out of the sight and reach of children
- Clean your inhaler on a weekly basis and if it becomes blocked as described under 'Cleaning your Evohaler'
- Do not use this medicine after the expiry date, which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.
- Do not store above 30 °C.
- Do not refrigerate or freeze.
- Store in the original package.
- Protect from frost and direct sunlight.
- If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.
- The metal canister is pressurised. Do not expose to temperatures higher than 50 °C. Do not puncture, break or burn it even when apparently empty.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Flixotide contains

- The active substance is fluticasone propionate
- The other ingredient is norflurane

What Flixotide Evohaler looks like and contents of the pack

- Flixotide Evohaler comprises an aluminium alloy canister sealed with a metering valve, actuator and dust cap.
- Each canister contains 120 doses of 125 or 250 micrograms of fluticasone propionate.

Manufacturer:

Flixotide Evohaler is manufactured by Glaxo Wellcome Ltd., Liverpool, UK or Glaxo Wellcome S.A., Burgos, Spain or Glaxo Wellcome Production, Evreux, France.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

PARALLEL PRODUCT AUTHORISATION NUMBER:

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Flixotide Evohaler 250 PPA 465/73/2

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