

Package Leaflet: Information for the user

Flixotide® Diskus® 50 micrograms, 100 micrograms, 250 micrograms, 500 micrograms 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, 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 this 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 other information

1 What Flixotide is and what it is used for

Flixotide contains fluticasone propionate which belongs to a group of medicines called corticosteroids (a group of synthetic hormones, often just called steroids). Flixotide works by reducing swelling and irritation in the lungs. It has an antiinflammatory 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 or 500 mcg strength Flixotide Diskus 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, lactose (which contains milk protein) 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 or pharmacist before using Flixotide.

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

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 Diskus comes in four 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 a Diskus.

- 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 below.
- You may not be able to taste or feel the powder on your tongue, even if you have taken it correctly
- **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 100 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.

Children (4 to 16 years of age)

The usual starting dose is 50 to 100 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 250mcg or 500mcg strength Flixotide Diskus 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 Diskus 250 micrograms and Flixotide Diskus 500 micrograms are not recommended for children 16 years and under.

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

Your doctor may give you a Flixotide Diskus of a higher strength 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 Diskus 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 Diskus properly or as prescribed may mean that it will not help your asthma as it should.
- The Diskus device holds blisters containing Flixotide as a powder
- There is a counter on top of the Diskus which tells you how many doses are left. It counts down to 0. The numbers 5 to 0 will appear in red to warn you when there are only a few doses left. Once the counter shows 0, your inhaler is empty.

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.

It is very important that you keep to your doctor's instructions as to how many blisters to take and how often to use your inhaler.

Using your inhaler

1 To open your Diskus, hold the outer case in one hand and put the thumb of your other hand on the thumbgrip. Push your thumb away from you as far as it will go. You will hear a click. This will open a small hole in the mouthpiece.



2 Hold your Diskus with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece.

Every time the lever is pulled back a blister is opened inside and the powder made ready for you to inhale. Do not play with the lever as this opens the blisters and wastes medicine.



3 Hold the Diskus away from your mouth, breathe out as far as is comfortable. Do not breathe into your Diskus. Do not breathe in again yet.

4 Put the mouthpiece to your lips; breathe in steadily and deeply through the Diskus with your mouth, not through your nose. Remove the Diskus from your mouth. Hold your breath for about 10 seconds or for as long as is comfortable. Breathe out slowly. You may not be able to taste or feel the powder on your tongue, even if you have used the Diskus correctly.



5 To close the Diskus, slide the thumbgrip back towards you, as far as it will go. You will hear a click. The lever will return to its original position and is reset. Your Diskus is now ready for you to use again.	
6. Afterwards, rinse your mouth with water and spit it out.	

Cleaning your Diskus

Wipe the mouthpiece of the Diskus with a dry tissue to clean it.

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. This can cause:
 - children and 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

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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

5 How to store Flixotid

- The Diskus is sealed in a foil overwrap which should only be opened when it is to be used for the first time. Once opened the foil overwrap should be discarded.
- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C. Store in a dry place.
- Do not use this medicine after the expiry date which is stated on the carton {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 to protect the environment.

6 Contents of the pack and other information

What Flixotide contains

- The active substance is fluticasone propionate
- The other ingredient is lactose (as monohydrate).

What Flixotide looks like and contents of the pack

Flixotide is a fine, white to off-white powder. The plastic Diskus device contains foil strips with blisters which contain fluticasone propionate and lactose. The blisters protect the powder for inhalation from the effects of the atmosphere.

Each blister contains 50 micrograms, 100 micrograms, 250 micrograms or 500 micrograms fluticasone propionate, and lactose which acts as the 'carrier'.

The 50, 100, 250 or 500 micrograms Flixotide packs contain twenty eight or sixty blisters. Not all pack sizes may be marketed.

The device has a counter which tells you the number of blisters remaining. It counts down from 28 or 60 to 0. To show when the last five blisters have been reached, the numbers appear in red. When the counter shows 0, your inhaler is empty and should be disposed of.

Marketing Authorisation Holder:

GlaxoSmithKline (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24

Manufacturer:

Glaxo Wellcome Production
Zone Industrielle No. 2
23 Rue Lavoisier
27000 Evreux
France

This leaflet was last revised in August 2023

Flixotide and Diskus are registered trade marks of the GSK group of companies.

©2023 GSK group of companies. All rights reserved.