Using Flixotide Accuhaler

Flixotide Accuhaler comes in four different strengths. Your doctor will have decided which strength you need. Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Using this medicine

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

- 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
- Do not play with the powder or put the powder in your mouth if you have taken it incorrectly
- 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 micrograms twice a day.

Moderate to severe asthma
- The usual starting dose is 250 to 500 micrograms twice a day.
- The most taken should be 1000 micrograms twice a day.

Children (4 to 16 years of age)
- The usual starting dose is 50 micrograms twice a day.
- The most taken should be 200 micrograms twice a day.

Flixotide 250 micrograms Accuhaler is not recommended for children 16 years and under.

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

Your doctor may give you a Flixotide Accuhaler 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 Accuhaler 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 fitting.

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 Accuhaler properly or as prescribed may mean that it will not help your asthma as it should.
- The Accuhaler device holds blisters containing Flixotide as a powder.
- There is a counter on top of the Accuhaler 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.

Your doctor may have told you to take more than this as an emergency treatment if your wheezing or breathing gets very bad. 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. Inside the carton, your Accuhaler is provided in a sealed foil wrapper. Open the foil wrapper, tear along the jagged edge, then remove the Accuhaler, and throw the wrapper away. If you have trouble tearing the foil, do not use scissors or any other sharp objects as you may harm yourself or the Accuhaler. Ask someone to help you.

2. To open your Accuhaler, 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.

3. Hold your Accuhaler 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.

4. Hold the Accuhaler away from your mouth, breathe out as far as is comfortable. Do not breathe into your Accuhaler. Do not breathe in again yet.
5. Put the mouthpiece to your lips; breathe in steadily and deeply through the Accuhaler with your mouth, not through your nose. Remove the Accuhaler from your mouth. Hold your breath for about 10 seconds or for as long as is comfortable. Breathe out slowly.

6. To close the Accuhaler, 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 Accuhaler is now ready for you to use again. Afterwards, rinse your mouth with water and spit it out.

Cleaning your Accuhaler
Wipe the mouthpiece of the Accuhaler with a dry tissue to clean it.

If you use more Flixotide Accuhaler than you should
If you use more than you should, talk to your doctor as soon as possible. It is important that you take your dose as stated on the pharmacist’s label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you forget to use Flixotide Accuhaler
• 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 Accuhaler
• 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 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.

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 weals 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 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.

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)
• sore tongue or throat
• hoarseness of voice

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.

The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):
• Pneumonia and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increased sputum production, change in sputum colour, fever, chills, increased cough, increased breathing problems
• Brusing.

Rare (may affect up to 1 in 1,000 people)
• thrush (candidiasis) in the oesophagus.

Very rare (may affect up to 1 in 10,000 people)
• sleeping problems or feeling worried, over-excited and irritable. These effects are more likely to occur in children
• joint pains
• indigestion
• level of sugar (glucose) in your blood may be increased
• the way steroids are produced by your body may be affected when using Flixotide Accuhaler. 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.

Although the frequency is not known, the following side effects may also occur:
• depression, feeling restless or nervous. These effects are more likely to occur in children.
• nosebleeds
• blurred vision

Talk to your doctor as soon as possible if:
• after 7 days of using Flixotide Accuhaler 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE FLIXOTIDE ACCUHALER
• Keep your Flixotide Accuhaler out of the sight and reach of children.
• Do not store above 30°C.
• Store in a dry place to protect from moisture.
• Store the Accuhaler in the foil wrapper until you are ready to use it for the first time. Once opened, the foil wrapper should be discarded.
• Do not use after the date shown as ‘EXP’ on the carton and device. The expiry date refers to the last day of that month.
• If the device doesn’t appear to be working properly, or is damaged, consult your pharmacist for advice.
• If you are told to stop taking this medicine, return your Flixotide Accuhaler to your pharmacist to be destroyed.
• Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Flixotide Accuhaler contains
The active substance is fluticasone propionate.
The other ingredient is lactose.

What Flixotide Accuhaler looks like and contents of the pack
Your Flixotide Accuhaler is a two tone orange and brown colour, circular device in moulded plastic containing inhalation powder and with a dose counter indicating number of doses remaining.

Flixotide Accuhaler is a plastic inhaler device containing a foil strip with 60 blisters. The device is provided in a sealed foil wrapper. Each blister contains powder for inhalation containing 250 micrograms of the active ingredient fluticasone propionate. Your medicine also contains lactose which acts as the carrier. The blisters protect the powder for inhalation from the effects of the atmosphere. The device has a counter which tells you the number of blisters remaining. It counts down from 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.

This leaflet does not contain the complete information about your medicine. If you have any questions, or are not sure about something, ask your doctor or pharmacist who have access to additional information.

Manufacturer
Flixotide Accuhaler is manufactured by: Glaxo Wellcome Production, Zone Industrielle No. 2, 23 Rue Lavoisier, 27000 Evreux, France.

Procured from within the EU and re-packaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR.

Product Licence holder: BR Lewis Pharmaceuticals Ltd., Kirk Sandall, Doncaster, DN3 1QR.

PL No: 08929/0102

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:
Product name: Flixotide 250 micrograms Accuhaler
Reference No: 08929/0102