

Package Leaflet: Information for the user

Fixotide™ Accuhaler™

50 micrograms,
100 micrograms,
250 micrograms,
500 micrograms
fluticasone propionate

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

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- 4 Possible side effects
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1 What Fixotide is and what it is used for

Fixotide Accuhaler is a plastic inhaler device containing a foil strip with 28 or 60 blisters. Each blister contains 50, 100, 250 or 500 micrograms of the active ingredient fluticasone propionate.

Fluticasone propionate belongs to a group of medicines called corticosteroids (often just called steroids). A very small dose of steroid is needed when it is inhaled. This is because it is inhaled straight to your lungs.

Fixotide works by reducing swelling and irritation in the lungs. They have what is called an 'anti-inflammatory action'.

Fixotide helps to prevent asthma attacks in people who need regular treatment. This is why they are sometimes called 'preventers'. They need to be used regularly, every day.

- Fluticasone propionate
- lactose or milk protein
- any of the other ingredients of Fixotide (listed in Section 6).

2 Before you use Fixotide

Do not use Fixotide if you are allergic (hypersensitive) to:

- fluticasone propionate
- lactose or milk protein
- any of the other ingredients of Fixotide (listed in Section 6).

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

Take special care with Fixotide

- Check with your doctor, nurse or pharmacist before taking your medicine if:
 - you have ever been treated for tuberculosis (TB).
 - you are using Fixotide 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.
 - If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Fixotide.

Taking other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken 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)
- medicines used to treat fungal infections (such as ketoconazole).

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

Using Fixotide with food and drink

You can use Fixotide at any time of day, with or without food.

Pregnancy and breast-feeding

Talk to your doctor before using this medicine if you are pregnant, might become pregnant or are breast-feeding.

Driving and using machines

Fixotide is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Fixotide
Fixotide contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before using this medicine.

3 How to use Fixotide

Fixotide comes in four different strengths. Your doctor will have decided which strength you need. Always use Fixotide exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

Using this medicine

The medicine in Fixotide 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
- You should be able to taste the powder on your tongue 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 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.
- Fixotide Accuhaler 250 micrograms and Fixotide Accuhaler 500 micrograms are not recommended for children 16 years and under. It is recommended that children being treated with steroids, including Fixotide Accuhaler have their height checked regularly by their doctor. Your doctor may give you a Fixotide 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 Fixotide 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 Fixotide Accuhaler properly or as prescribed may mean that it will not help your asthma as it should
- The Accuhaler is provided in a sealed foil wrapper. The wrapper provides protection from moisture and should only be opened when you are ready to use it for the first time. Once opened the foil wrapper should be discarded.
- The Accuhaler device holds blisters containing Fixotide 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. To open this 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.

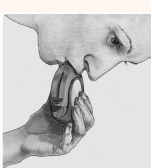


3 Hold your Accuhaler with the mouthpiece towards you. You can hold it in either your right or left hand. Slide the lever away from you as far as it will go. You will hear a click. This places a dose of your medicine in the mouthpiece. Every time the lever is pulled back a blister is opened inside and the powder made ready for you to inhale. Do not play with the lever as this opens the blisters and wastes medicine.



4 Hold the Accuhaler away from your mouth, breathe out as far as is comfortable. Do not breathe into your Accuhaler. Do not breath 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.



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Cleaning your Accuhaler

Wipe the mouthpiece of the Accuhaler 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. 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

- 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 (affects less than 1 in 100 people) - the signs include skin rashes, redness, itching or weals like nettle rash or hives
- severe allergic reactions (affects less than 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.

Other side effects include:

- **Very common** (affects more than 1 in 10 people)
- thrush in the mouth and throat

Common

- 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
- Bruising.

Very rare

- affects less than 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. 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.

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5 How to store Flixotide

- Store in a dry place to protect from moisture
- Keep out of the reach and sight of children
- Do not store above 30°C
- 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 Flixotide after the expiry date which is stated on the carton (EXP). The expiry date refers to the last day of that month
- 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 Further information

What Flixotide contains

- The active substance is fluticasone propionate
- The other ingredient is lactose.

What Flixotide looks like and contents of the pack

The plastic Accuhaler device is provided in a sealed foil wrapper. The Accuhaler 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 sixty blisters.

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.

Marketing Authorisation Holder:

Glaxo Wellcome UK Limited trading as:
Allen & Hanburys
Stockley Park West

UK/bridge
Midlsex
UB11 1BT

Manufacturer:

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

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name

Flixotide 50
Flixotide 100
Flixotide 250
Flixotide 500

Reference numbers

10949/0226

This is a service provided by the Royal National Institute of Blind People.

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