

FLIXOTIDE® ACCUHALER®, FLIXOTIDE® JUNIOR ACCUHALER®

Fluticasone propionate

Consumer Medicine Information

Please read this leaflet carefully before you start Flixotide Accuhaler or Flixotide Junior Accuhaler. (simply called Flixotide Accuhaler in this document.)

What is in this leaflet

This leaflet answers some common questions about Flixotide Accuhaler. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Flixotide Accuhaler against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Flixotide Accuhaler is used for

Flixotide Accuhaler contains a medicine called fluticasone propionate. This medicine belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. They are not 'anabolic steroids' which are the steroids sometimes misused by athletes.

Your Flixotide Accuhaler provides a measured amount of steroid for you to breathe into your lungs. By using your Flixotide Accuhaler regularly every day, the medicine reduces the swelling and irritation in the walls of the small air passages in your lungs. Your Flixotide Accuhaler contains the type of asthma medicine known as a 'preventer'. It does not give immediate relief from an asthma attack and may take up to a week to start to work. If your shortness of breath or wheeze does not get better after 7 days, tell your doctor. When used every day, your Flixotide Accuhaler helps to ease breathing problems and prevent asthma attacks.

This medicine is only one part of a general plan to help you manage your asthma. You should discuss this plan with your doctor. You may also be using a 'reliever puffer'. Keep using it according to your doctor's advice. Ask your doctor to check your treatment regularly.

Ask your doctor if you have any questions about why Flixotide Accuhaler has been prescribed for you.

The medicine in Flixotide Accuhaler is not addictive.

Flixotide Accuhaler generally does not cause any problems with your ability to drive a car or operate machinery.

Before you use Flixotide Accuhaler

When you must not use it

- **Do not use Flixotide Accuhaler if you have ever had an allergic reaction to fluticasone propionate, lactose or milk protein.** Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

- **Do not use Flixotide Accuhaler if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should. It is important that asthma is managed well during pregnancy and you should not stop your medicine without asking your doctor.**

Your doctor will discuss the risks and benefits of using Flixotide Accuhaler if you are pregnant or breastfeeding.

- **Do not use Flixotide Accuhaler after the expiry date (EXP) printed on the pack.**

If you use it after the expiry date has passed, it may not work as well.

- **Do not use Flixotide Accuhaler if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be using Flixotide Accuhaler, talk to your doctor.

Before you start to use it

You must tell your doctor if:

- **you are taking other steroid medicines by mouth or inhalation. If you are already taking steroid tablets, you should carry a warning card about needing extra oral steroids during periods of stress eg. worsening asthma attacks, chest infections, surgery, trauma and other major illnesses occurring at the same time. Discuss this with your doctor.**
- **you have ever had to stop taking other asthma medicines.**
- **you have tuberculosis (TB) of the lung or other long term lung infection.**
- **you are allergic to foods, dyes, preservatives or any other medicines.**

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. For example, medicines like ketoconazole, used to treat fungal infection, and ritonavir used to treat HIV infection, may affect how Flixotide Accuhaler works. If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

How to use Flixotide Accuhaler

How to use it

Remember that the medicine in your Flixotide Accuhaler is taken by inhalation only.

You will find the instructions on how to use your Flixotide Accuhaler in the pack. Follow the instructions carefully.

How much to use

The pharmacist's label will usually tell you how many inhalations and how often to use your Flixotide Accuhaler. If you are not sure, ask your doctor or pharmacist.

For adults: The usual dose is in the range of 100 to 1000 micrograms twice daily.

For children: The usual dose is in the range of 50 to 100 micrograms twice daily.

Your doctor will decide what dose you should take, how often you should take it, and what strength of Flixotide Accuhaler you should use.

You should visit your doctor or pharmacist regularly to check that you are using your Flixotide Accuhaler in the right way. If you are not breathing the medicine in correctly, the medicine may not be helping you as much as it could.

When not to use it

Do not use your Flixotide Accuhaler to treat a sudden attack of breathlessness. You will need a different kind of medicine called a 'reliever' which your doctor will have told you to take.

How long to use it

You must use your Flixotide Accuhaler every day. Do not stop using it, even if you feel better, unless your doctor tells you.

If you forget to use it

You must use your Flixotide Accuhaler every day. If you forget to take a dose, do not worry. Just take the next dose when it is due.

Do not take a double dose to make up for the dose that you missed.

If you become wheezy or feel tight in the chest before the next dose is due, use a 'reliever puffer' in the usual way. You should get relief from your 'reliever puffer' within a few minutes.

If you have used too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, if you think you may have taken too much of your medicine, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Flixotide Accuhaler

Things you must do

Tell your doctor or pharmacist that you are using Flixotide Accuhaler if you are about to be started on any new medicines.

If you have to go into hospital for an operation, take your Flixotide Accuhaler with you and tell the doctor what medicine(s) you are taking.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that your medicine was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop using Flixotide Accuhaler, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Flixotide Accuhaler to treat any other complaints unless your doctor says to.

If your Flixotide Accuhaler does not have the usual effect

If your chest condition gets worse, tell your doctor. Your doctor may tell you to take extra puffs of your Flixotide Accuhaler or add another medicine (such as a 'reliever puffer') to your treatment.

IMPORTANT: IF YOUR BREATHING SUDDENLY BECOMES MORE DIFFICULT JUST AFTER YOU HAVE USED YOUR FLIXOTIDE ACCUHALER, YOU WILL NEED TO USE A 'RELIEVER PUFFER' AND TELL YOUR DOCTOR IMMEDIATELY.

Tell your doctor as soon as possible if:

- your 'reliever puffer' does not help your breathing as much as usual
- the effect of your 'reliever puffer' does not last as long as usual
- you need more puffs of your 'reliever puffer' than usual to get relief.

Side-Effects

Check with your doctor as soon as possible if you have any problems while using Flixotide Accuhaler, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Flixotide Accuhaler can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- a sore throat or tongue. This may be due to 'thrush' (candida infection)
- hoarseness or throat irritation

Tell your doctor or pharmacist immediately if you notice any of these signs.

For these, it may be helpful to rinse your mouth with water and spit it out after using your Flixotide Accuhaler. Your doctor may prescribe treatment for the 'thrush' in your mouth while you continue to use your Flixotide Accuhaler.

It is possible that some people, particularly those taking higher doses of Flixotide Accuhaler for a long time, may rarely suffer from the following side-effects:

- rounded face
- loss of bone density
- eye problems (eg. cataract, glaucoma)
- slowing of growth in children. It is unclear what, if any, difference this makes to their final height
- soreness in the oesophagus.

Taking high doses of steroids for a long time this could affect the adrenal glands, which make the body's own steroid. Your doctor may do tests to check how the adrenal glands are working. Your doctor will be able to answer any questions you may have.

It is important that:

- treatment with Flixotide Accuhaler should not be stopped suddenly
- all doctors treating you are aware that you are on inhaled steroids. If your body is stressed by, for example, severe infection, surgical operation, an accident etc, you may need steroid tablets or injections for a time.

Very rarely the person taking the medicine may feel anxious, have disturbed sleep or notice increased irritability (mainly in children).

There may be an increase in the amount of sugar (glucose) in your blood. If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetes treatment may be required.

If you feel unwell in any other way or have any symptoms that you do not understand, you should ask your doctor immediately.

Ask your doctor or pharmacist to answer any questions you may have.

If you think you are having an allergic reaction to Flixotide Accuhaler, tell your doctor immediately or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth, tongue or throat
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

After using Flixotide Accuhaler

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Store Flixotide Accuhaler in the foil overwrap until you are ready to use it for the first time. Once opened the foil overwrap should be discarded.

Keep Flixotide Accuhaler in a dry place away from heat (store below 30°C).

Do not leave it in the car or on window sills.

Heat can destroy some medicines.

Disposal

If your doctor tells you to stop using Flixotide Accuhaler, or the product has passed its expiry date, ask your pharmacist what to do with any Flixotide Accuhaler left over.

Product description

What Flixotide Accuhaler looks like

The Flixotide Accuhaler is a plastic device which contains a foil strip inside. The foil strip has pockets (called blisters) which contain your medicine. The Flixotide Accuhaler is packaged within a foil overwrap. The plastic device is labelled, "Flixotide Accuhaler".

Ingredients

Flixotide Accuhaler contains the medicine called fluticasone propionate. It also contains lactose powder as a non-active ingredient (which contains milk protein).

Flixotide Accuhaler is available in three strengths:

- Flixotide Junior Accuhaler 100 micrograms of fluticasone propionate in a blister
- Flixotide Accuhaler 250 micrograms of fluticasone propionate in a blister
- Flixotide Accuhaler 500 micrograms of fluticasone propionate in a blister

Each device contains 60 blisters. Your Flixotide Accuhaler has a dose counter which tells you how many doses are left. To let you know when you have reached the last five doses, the numbers appear in red.

Other types of asthma medicines

Your Flixotide Accuhaler contains the kind of asthma medicine known as a 'preventer'. There are other types of inhalers that relieve your breathing problems when you are wheezing or your chest is tight. These medicines are called 'relievers'. Your doctor may tell you to use a 'reliever' in addition to your Flixotide Accuhaler.

Sponsor

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Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away. You may need to read it again.

This leaflet was prepared on 3 June 2014.

The information provided applies only to: Flixotide® Accuhaler® and Flixotide® Junior Accuhaler®.

Flixotide and Accuhaler are registered trade marks of the GlaxoSmithKline group of companies.

Flixotide (fluticasone propionate):

- Junior Accuhaler 100 micrograms of fluticasone propionate in a blister, 60 doses, AUST R 58439
- Accuhaler 250 micrograms of fluticasone propionate in a blister, 60 doses, AUST R 58438

- Accuhaler 500 micrograms of fluticasone propionate in a blister, 60 doses, AUST R 58437

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