

FLIXOTIDE[®] INHALER

Fluticasone propionate (CFC-Free) Inhaler 50, 125 or 250µg per actuation

Consumer Medicine Information

Please read this leaflet carefully before you start using Flixotide (CFC-free) Inhaler.

What is in this leaflet?

This leaflet answers some common questions about Flixotide Inhaler. 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 Inhaler 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 Inhalers ('puffers') are used for

You may know your Inhaler better as a 'puffer'. Flixotide

puffers contain 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 puffer provides a measured amount of steroid for you to breathe into your lungs. By using your Flixotide puffer regularly every day, the medicine reduces the swelling and irritation in the walls of the small air passages in your lungs. Your Flixotide puffer 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 puffer 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 a Flixotide puffer has been prescribed for you.

The medicine in Flixotide puffers is not addictive.

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

Before you use your Flixotide puffer

When you must NOT use it

Do not use your Flixotide puffer if you have ever had an allergic reaction to fluticasone propionate or any of the ingredients listed at the end of this leaflet.

See "Side Effects" section for symptoms of an allergic reaction.

- **Do not use your Flixotide puffer 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 your Flixotide puffer if you are pregnant or breastfeeding.

- **Do not use your Flixotide puffer 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 your Flixotide puffer if the packaging is torn or shows signs of tampering.**
- **If you're not sure whether you should be using a Flixotide puffer, talk to your doctor.**

Before you start using your puffer

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. Discuss this with your doctor.
- you are taking ritonavir, a medicine used in the treatment of HIV(AIDS)
- 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.
- 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 other medicines work. Your doctor or pharmacist will be able to tell you what to do when using your Flixotide puffer with other medicines.

Using your Flixotide puffer

How to use it

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

You will find the instructions on how to use your Flixotide puffer on the leaflet 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 puffer. If you are not sure, ask your doctor or pharmacist.

For adults and children over 16 years of age: The usual dose is in the range of 100 to 1000 micrograms twice daily.

For children over 4 years: The usual dose is in the range of 50 to 200 micrograms twice daily.

For children from 1 to 4 years of age, the usual dose is 100 micrograms twice daily. The medicine is usually breathed in using a device called a 'spacer', with a facemask. Your doctor or pharmacist will explain to you what this is and how to use it. Your doctor will decide what dose you should take, how often you should take it, and what strength of Flixotide puffer you should use.

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

If you find it difficult to breathe in and press your Flixotide puffer at the same time, talk to your doctor or pharmacist. It may be better for you to use something called a 'spacer device' with your Flixotide puffer. Your doctor or pharmacist will explain to you what this is and how to use it.

If you change the make of spacer you use this may alter the amount of drug delivered to the lungs. You should let your doctor know if your asthma symptoms worsen.

When not to use it

Do not use your Flixotide puffer 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 puffer 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 puffer 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 (0800 POISON or 0800 764 766) 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 your Flixotide puffer

Things you must do

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

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

All doctors treating you need to be 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.

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 your Flixotide puffer, 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 your Flixotide puffer to treat any other

complaints unless your doctor says to.

If your Flixotide puffer 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 puffer 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 puffer, 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 your Flixotide puffer, even if you do not think the problems are connected with the medicine, or are not listed in this leaflet.

Like other medicines, Flixotide puffers may 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

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

Rarely, Flixotide puffer can cause soreness in the oesophagus.

Very rarely, Flixotide puffer may cause swelling of the throat and face. There may also be an increase in sugar (glucose) in your blood.

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

Taking high doses of steroids for a long time, may affect bone density, or affect the rate of growth in children. It is unclear what, if any, difference this makes to their final height. Taking high doses of steroids for a long time 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.

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 your Flixotide puffer, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth, face and throat
- difficulty in breathing, shortness of breath
- 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 your Flixotide puffer

Storage

Straight after use, replace the mouthpiece cover firmly and

click it into position. Do not use excessive force.

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.

Keep your Flixotide puffer away from heat (store below 30°C), and bright sunlight.

Keep your Flixotide puffer away from frost. Do not put it in the refrigerator.

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

Heat can destroy some medicines.

If your Flixotide puffer becomes very cold, it may not work properly. To warm it, pull out the metal can from its plastic holder and warm it in your hand for a few minutes. Do not warm the can in any other way. Push the can firmly back into its holder before using.

GlaxoSmithKline inhalers are designed to give out a metered dose of medication until they are empty.

You should keep a record of the number of doses you have used up.

On average, GlaxoSmithKline includes 10% more active doses in each puffer than is specified on the label.

Floating the puffer in water to estimate the amount of doses left in the puffer is not recommended. Water may enter the valve in the puffer, which may affect the accuracy of later doses. The humidity from the water may also

encourage bacteria to grow in the valve.

You should always carry a spare puffer.

Disposal

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

WARNING: The metal can is pressurised. Do not burn it or puncture it, even when it is empty.

You can recycle the plastic holder and cap of your Flixotide puffer with other plastic things.

Product Description

What Flixotide puffer looks like

A Flixotide puffer consists of a plastic holder which contains a small metal can. The holder has a mouthpiece which is covered by a cap.

Ingredients

Flixotide puffers contain the medicine called fluticasone propionate. They are available in the following strengths:

- Flixotide Inhaler (CFC-free), containing 50 micrograms of fluticasone propionate in each puff.
- Flixotide (CFC-free) Inhaler, containing 125

micrograms of fluticasone propionate in each puff.

- Flixotide (CFC-free) Inhaler, containing 250 micrograms of fluticasone propionate in each puff.

Flixotide (CFC-free) puffers contain the inactive ingredient norflurane.

Each Flixotide can contains 120 puffs.

Other types of asthma medicines

Your Flixotide puffer 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 puffer.

Manufacturer

Your Flixotide puffer is supplied by:

GlaxoSmithKline NZ Ltd

Private Bag 106600

Downtown Auckland

New Zealand

Ph: (09) 367 2900

Fax (09) 367 2910

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.

The information provided applies to Flixotide[®] puffers.

Flixotide is a registered trade mark of the GlaxoSmithKline Group of Companies.

This leaflet is copyrighted to GlaxoSmithKline and may be reproduced but not altered in any way.

Version 3.0, 17 December 2014