

FLIXOTIDE EVOHALER

Fluticasone Propionate (50mcg, 125mcg)

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What FLIXOTIDE is used for

The name of your medicine is Flixotide Evohaler.

Flixotide Evohaler delivers your medicine as an aerosol spray for you to inhale directly into your lungs where it is needed.

Your doctor has chosen this medicine to suit you and your condition.

Flixotide Evohaler is used to treat and prevent asthma in people who need regular treatment.

How FLIXOTIDE works

Fluticasone propionate is one of a group of medicines called corticosteroids which are often referred to simply as steroids. Corticosteroids are used to treat asthma because they have an anti-inflammatory action. They reduce the swelling and irritation in the walls of the small air passages in the lungs and so ease breathing problems.

Corticosteroids also help to prevent attacks of asthma. Fluticasone propionate should not be confused with other steroids such as anabolic steroids misused by some athletes and taken as tablets or injection.

Before you use FLIXOTIDE

- When you must not use it

- If you are allergic to Flixotide, fluticasone propionate or any of the other ingredients in this medicine.

Do not use this medicine to treat a sudden attack of breathlessness - it will not help you. You will need a different kind of medicine. If you have more than one medicine be careful not to confuse them.

- Before you start to use it

If you answer 'yes' to any of the following questions tell your doctor about this before taking your medicine.

- Are you pregnant or likely to become pregnant soon?
- Are you breast-feeding?
- Are you being or have you ever been treated for tuberculosis (TB), a bacterial infection that affects mainly the lungs?

Pneumonia (lung infection) has been reported commonly in COPD patients.

In rare instances, treatment with Flixotide Evohaler may affect the normal production of steroids in the body. This is more likely to happen if high doses are being used over a long period of time. One of the rare effects is that children and adolescents may grow more slowly than others.

Children and adolescents who are receiving treatment over a long period of time will have their height checked regularly by their doctor. Other effects can include symptoms caused by an

excess of steroid in the body (known as Cushing's syndrome), thinning of the bones and certain eye disorders (known as cataract and glaucoma). If you have just started using a spacer with your inhaler then your doctor may reduce your dose to decrease the risk of you getting these side effects.

If 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.

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.

If your breathing or wheezing gets worse straight after using your inhaler, immediately use a fast-acting 'reliever' inhaler. Stop using Flixotide Evohaler and talk to your doctor straight away.

- Taking other medicines

In some cases, inhaled fluticasone propionate may not be suitable to use with other medicines (e.g. some HIV or oral anti-fungal medicines). You must not take inhaled fluticasone propionate if you are receiving a medicine called ritonavir or ketoconazole, without first consulting your doctor. Make sure your doctor knows what other medicines you are taking, including those that you have bought yourself.

How to use FLIXOTIDE

- How much to use

Take your medicine as your doctor has told you. The label on it will usually tell you how much to take and how often. If you are not sure ask your doctor, nurse or pharmacist.

The usual dose is:

Asthma:

Adults and children over 16 years: 100 to 1000 micrograms twice a day.

Children and adolescents from 4 years and above: 50 to 200 micrograms twice a day.

Children from 1 to 4 years: 100 micrograms twice a day.

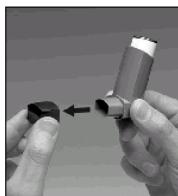
Read these directions carefully before taking your medication.

Testing your inhaler:

Before using for the first time or if your inhaler has not been used for a week or more remove the mouthpiece cover by gently squeezing the sides of the cover, shake the inhaler well, and release two puffs into the air to make sure that it works.

Using your inhaler:

1. Remove the mouthpiece cover by gently squeezing the sides of the cover.
2. Check inside and outside of the inhaler including the mouthpiece for the presence of loose objects.



3. Shake the inhaler well to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.



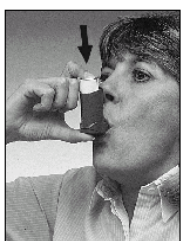
4. Hold the inhaler upright between fingers and thumb with your thumb on the base, below the mouthpiece.



5. Breathe out as far as is comfortable and then place the mouthpiece in your mouth between your teeth and close your lips around it but do not bite it.



6. Just after starting to breathe in through your mouth press down on the top of the inhaler to release Flixotide while still breathing in steadily and deeply.



7. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler. Continue holding your breath for as long as is comfortable.



8. If you take further puffs keep the inhaler upright and wait about half a min before repeating steps 3 to 7.

9. Afterwards, rinse your mouth with water and spit it out.

10. Replace the mouthpiece cover by firmly pushing and snapping the cap into position.

IMPORTANT:

Do not rush stages 5, 6 and 7. It is important that you start to breathe in as slowly as possible just before operating your inhaler. Practise in front of a mirror for the first few times. If you see "mist" coming from the top of your inhaler or the sides of your mouth you should start again from stage 2.

If your doctor has given you different instructions for using your inhaler, please follow them carefully. Tell your doctor if you have any difficulties.

Cleaning:

Your inhaler should be cleaned at least once a week.

1. Remove the mouthpiece cover.
2. Do not remove the canister from the plastic casing.
3. Wipe the inside and outside of the mouthpiece with a dry cloth or tissue.
4. Replace the mouthpiece cover.

Do not put the metal canister into water.

- When to use it

It may take 4 to 7 days before you notice the benefit from this medicine. It is very important that you use it regularly every day.

- How long to use it

Do not stop treatment even if you feel better unless told to do so by your doctor.

- If you forget to use it

If you miss a dose just take the next dose when it is due.

- If you use too much (overdose)

Tell your doctor as soon as possible if you accidentally take a larger dose than you were told to.

If you have used larger doses for a long period of time, you should talk to your doctor or pharmacist for advice. This is because larger doses of Flixotide may reduce the amount of steroid hormones produced by the adrenal gland.

While you are using it

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

Flixotide Inhaler produces a fine mist which you must inhale into your lungs. Make sure that you know how to use the inhaler properly. If you have any problems ask your doctor, nurse or pharmacist. Flixotide Evohaler must only be breathed in through the mouth.

Some people find it difficult to release a puff of medicine just after they start to breathe in. A spacer device may help to overcome this problem. Your doctor, nurse or pharmacist will be able to advise you about this.

- Things you must not do

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.

- Things to be careful of

If your breathing or wheezing gets worse straight after taking your medicine, stop using it immediately and tell your doctor as soon as possible.

If your shortness of breath and wheeze actually gets worse over several days, despite taking your new medicine, or if you find you are increasing the use of your other inhaled medicines, tell your doctor immediately.

Side Effects

Some people can be allergic to medicines. If you have any of the following symptoms soon after taking Flixotide Evohaler, stop taking this medicine and tell your doctor immediately.

- Sudden wheeziness and chest pain or tightness.
- Swelling of eyelids, face, lips, tongue or throat.
- Lumpy skin rash or "hives" anywhere on the body.

Most people taking this medicine find that it causes no problems. As with all medicines, some people may find that it causes side effects.

A few people very occasionally find that their throat or tongue becomes sore or that their voice becomes hoarse after inhaling

this medicine. Rinsing the mouth with water and spitting it out immediately after each dose may help.

Tell your doctor but do not stop treatment unless told to do so. It is possible that some patients, particularly those taking higher doses of this type of medication, may very rarely suffer from the following side effects: rounded face, loss of bone density, eye problems and slowing of growth 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.

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

If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of FLIXOTIDE

- Storage

Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force. Store the inhaler at room temperature below 30°C. Protect from frost and direct sunlight.

If the inhaler gets very cold, take the metal canister out of the plastic case and warm it up in your hands for a few minutes before use. Never use anything else to warm it up.

Do not use after the date shown as "Exp" on the carton and label. Keep your inhaler where children cannot reach it. It may harm them.

Warning - The metal canister is pressurised. Do not expose to temperatures higher than 50°C. Do not puncture, break or burn even when apparently empty.

- Disposal

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.

Product Description

- What it looks like

Flixotide 50 Evohaler and 125 Evohaler are pressurised metered-dose inhalers which deliver 50 micrograms and 125 micrograms of fluticasone propionate per actuation into the mouthpiece of a specially designed actuator.

Each canister of Flixotide 50 Evohaler supplies 120 actuations.

Each canister of Flixotide 125 Evohaler supplies 60 or 120 actuations.

- Ingredients

- Active ingredient(s)
Fluticasone propionate 50 and 125 micrograms.

- Inactive ingredient(s)
Hydroxyfluoroalkane 134a, 1, 1, 1, 2-tetrafluoroethane (HFA 134a).

- MAL number

Flixotide Evohaler 50mcg
MAL20021381ARZ
Flixotide Evohaler 125mcg
MAL20034218ARZ

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Product Registration Holder

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