

Fluticasone Cipla Inhaler

125 microgram and 250 microgram MDI

Fluticasone propionate

Consumer Medicine Information

Please read this leaflet carefully before you start using Fluticasone Cipla Inhaler.

What is in this leaflet

This leaflet answers some common questions about Fluticasone Cipla 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 Fluticasone Cipla 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 Fluticasone Cipla Inhalers ('puffers') are used for

You may know your Inhaler better as a 'puffer'. Fluticasone Cipla 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 Fluticasone Cipla puffer provides a measured amount of steroid for you to breathe into your lungs. By using your Fluticasone Cipla puffer regularly every day, the medicine reduces the swelling and irritation in the walls of the small air passages in your lungs.

Your Fluticasone Cipla 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 Fluticasone Cipla 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 Fluticasone Cipla puffer has been prescribed for you. The medicine in Fluticasone Cipla puffers is not addictive.

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

Before you use your Fluticasone Cipla puffer

When you must not use it

- **Do not use your Fluticasone Cipla puffer if you have ever had an allergic reaction to fluticasone propionate or any of the ingredients listed at the end of this leaflet.** 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 your Fluticasone Cipla puffer if you are pregnant, trying to become pregnant or breast-feeding, 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 Fluticasone Cipla puffer if you are pregnant or breastfeeding.

- **Do not use your Fluticasone Cipla 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 Fluticasone Cipla puffer if the packaging is torn or shows signs of tampering.**
- **If you're not sure whether you should be using an Fluticasone Cipla puffer, 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 Fluticasone Cipla puffer works. If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

How to use your Fluticasone Cipla puffer

Testing your inhaler

When you use the inhaler for the first time, you should test if it works properly.

1. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.
2. To make sure that it works, shake the inhaler well, point the mouthpiece away from you and press the canister to release four puffs into the air. If you have not used the inhaler for a week or more, release two puffs of medicine into the air.

How to use it

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

You will find the instructions on how to use your Fluticasone Cipla puffer on the leaflet in the pack. Follow the instructions carefully.

Cleaning your inhaler

To prevent your inhaler from blocking, it is important to clean it at least once a week.

Hand-warming instruction

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

How much to use

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

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

For children from 1 to 16 years of age:

Fluticasone Cipla puffer is not for use in patients aged under 16 years. A lower strength fluticasone (50 micrograms) inhalation can be available from other brand/s.

Your doctor will decide what dose you should take, how often you should take it, and what strength of Fluticasone Cipla puffer you should use.

You should visit your doctor or pharmacist regularly to check that you are using your Fluticasone Cipla puffer 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.

If you find it difficult to breathe in and press your Fluticasone Cipla Inhaler at the same time, talk to your doctor or pharmacist. It may be better for you to use something called a 'spacer' with your Fluticasone Cipla 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.

If you have any questions about using a spacer, ask your doctor or pharmacist.

When not to use it

Do not use your Fluticasone Cipla 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 Fluticasone Cipla 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 Fluticasone Cipla 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 (telephone 131126) 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 Fluticasone Cipla puffer

Things you must do

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

If you have to go into hospital for an operation, take your Fluticasone Cipla puffer 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 your Fluticasone Cipla 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 Fluticasone Cipla puffer to treat any other complaints unless your doctor says to.

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

Like other medicines, Fluticasone Cipla 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

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 Fluticasone Cipla puffer. Your doctor may prescribe treatment for the 'thrush' in your mouth

while you continue to use your Fluticasone Cipla puffer.

It is possible that some people, particularly those taking higher doses of Fluticasone Cipla puffer 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 your Fluticasone Cipla puffer 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 your Fluticasone Cipla puffer, 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 your Fluticasone Cipla puffer

Storage

Straight after use, replace 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 Fluticasone Cipla puffer away from heat (store below 25°C, and bright sunlight).

Keep your Fluticasone Cipla 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 Fluticasone Cipla 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.

Disposal

If your doctor tells you to stop using your Fluticasone Cipla puffer, or the product has passed its expiry date, ask your pharmacist what to do with any Fluticasone Cipla 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 Fluticasone Cipla puffer with other plastic things.

Product description

What Fluticasone Cipla puffer looks like

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

Ingredients

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

Fluticasone Cipla Inhaler, containing 125 micrograms of fluticasone propionate in each puff.

Fluticasone Cipla Inhaler 125 microgram are a rigid, aluminium, container fitted with a metered dose valve, containing a white homogeneous suspension, fitted to a plastic actuator with a white body and yellow coloured cap.

Fluticasone Cipla Inhaler, containing 250 micrograms of fluticasone propionate in each puff.

Fluticasone Cipla Inhaler 250 microgram are a rigid, aluminium, container fitted with a metered dose valve, containing a white homogeneous suspension, fitted to a plastic actuator with a white body and yellow coloured cap.

Fluticasone Cipla puffers contain the inactive ingredient norflurane.

Cans containing 120 puffs is available.

Other types of asthma medicines

Your Fluticasone Cipla 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 Fluticasone Cipla puffer.

Sponsor

Cipla Australia Pty Ltd.,
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South Melbourne, VIC 3205

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.

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