

Floair Inhaler

Consumer Medicine Information

Fluticasone Propionate

50 mcg, 125 mcg, 250 mcg suspension for inhalation
120 ACTUATIONS

What is in this leaflet

The information enclosed answers several general questions about your Floair Inhaler. This leaflet does not include all the accessible information on Floair Inhaler. All medication has benefits and risks. Your doctor will have considered the risks of you using Floair Inhaler against the benefits expected. Discuss with your doctor or pharmacist any concerns you may have.

This leaflet was last updated on the date at the end of this leaflet.

Keep this information with the medicine and refer to this leaflet if you have any queries.

Floair Inhaler is one component of your asthma plan to help control and manage your condition. Your asthma plan should be checked by your doctor on a regular basis. Discuss any concerns about your plan with your doctor.

What your Floair Inhaler is used for

Floair Inhaler contains Fluticasone propionate, a steroid that prevents asthma attacks.

The corticosteroids in your Floair Inhaler are not the same as anabolic steroids that have been known to have been exploited by sports people. The anti-inflammatory effect in your medication is due to the corticosteroids.

Each Floair Inhaler delivers either 50 mcg, 125 mcg or 250 mcg of Fluticasone propionate per actuation (or dose). Your Floair Inhaler contains 120 actuations.

This inhaler may have a body or cap colour that is different to your previous inhaler. This does not affect the way it works.

Each Floair Inhaler also contains the propellant HFA-134a, less than 0.002g ethanol, and less than 0.00005mg soy lecithin per actuation.

Floair Inhaler does not contain any chlorofluorocarbon (CFC) propellants. It does contain a non-CFC propellant, known as HFA-134a. If you have previously used another inhaler, you might notice that the spray from Floair Inhaler tastes or feels different in your mouth, or that the inhaler sounds different when sprayed. This does not affect the way your inhaler works.

Floair Inhaler is a “preventer” inhaler that reduces irritation and swelling in the air passages in your lungs. If you have asthma, taking Floair Inhaler each morning and evening will help prevent asthma attacks.

Floair Inhaler helps to stop breathlessness and wheezing coming on. It does not work once you are breathless or wheezy.

You should always carry your “reliever” inhaler (e.g. Salbutamol) with you. In the event of an asthma attack, use your “reliever” inhaler, NOT Floair Inhaler.

Before you use your Floair Inhaler

If you have any concerns about using your Floair Inhaler, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Do not give it to anyone else even if their symptoms are the same as yours, as it may harm them.

Tell your doctor before using Floair Inhaler if you:

- Are allergic to Fluticasone propionate or any of the other ingredients in your inhaler;
- Have had to discontinue Floair Inhaler in the past or other medication for asthma;
- Have an allergy to dyes, preservatives, foods or other medication;
- Are pregnant or intending on becoming pregnant;
- Are breastfeeding;
- Have been taking or are currently taking steroid tablets or have had a steroid injection;
- Have ever had tuberculosis (TB) or another long-term lung infection;
- Have diabetes;
- Have an infection of the lungs or chest;
- Have heart problems such as heart failure, an irregular heart beat;
- an abnormal bulging of a blood vessel wall (an aneurysm);
- high blood pressure;
- an overactive thyroid gland which can cause increased appetite, weight loss or sweating;
- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm;
- poor adrenal gland function;
- liver problems;
- Are taking ANY other medicines.

Using other medicines

Tell your doctor, pharmacist or asthma nurse if you are taking, have recently taken or might take any other medicines. If you use this inhaler with some other medicines the effect of this inhaler or the other medicine may be altered.

Tell your doctor, pharmacist or asthma nurse if you are taking:

- beta-blockers (such as atenolol to treat blood pressure, sotalol to treat an irregular heartbeat, metoprolol to treat a fast heart beat or timolol eye drops to treat glaucoma);
- other medicines used to treat asthma or breathing conditions (such as theophylline);
- medicines containing adrenaline or related substances (including other beta-agonists like salbutamol);
- antihistamines;
- diuretics;
- medicines used to treat heart failure (such as digoxin);
- medicines to treat abnormal heart rhythms (such as quinidine, disopyramide, procainamide);
- medicines to treat symptoms of depression or mental disorders such as monoamine oxidase inhibitors, tricyclic antidepressants, or you have taken any of these types of medicine in the last two weeks;
- medicines used to treat psychiatric or mental disorders (phenothiazines or antipsychotics);
- other medicines containing steroids;
- antifungal medicines (such as ketoconazole or itraconazole);
- medicines used to treat viral infections including HIV (for example ritonavir, atazanavir, indinavir, nelfinavir or saquinavir);
- antibiotics (such as clarithromycin or furazolidone);
- medicine to treat Parkinson's disease (levodopa);
- medicine to treat an underactive thyroid gland (levothyroxine);
- medicine to treat Hodgkin's disease (procarbazine);
- oxytocin.

If you are going to have an operation under a general anaesthetic, please tell the doctor at the hospital that you are using this inhaler.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby ask your doctor or asthma nurse for advice about using your Floair Inhaler. Your doctor or asthma nurse will advise you if you should take this medicine.

Driving and using machines

This medicine is unlikely to affect your ability to drive or use machines.

Using your Floair Inhaler

To get the full benefit from your Floair Inhaler, you need to take it regularly in the morning and evening.

Floair Inhaler comes in three different strengths. Your doctor will have decided which strength you need and how many doses to take. The dispensing label should tell you how much to take and how often.

If you find it difficult to use your inhaler and breathe in at the same time, you may find a spacer device helpful. Ask your doctor or pharmacist about this.

Floair Inhaler should not be used to remedy any conditions other than what your doctor has prescribed it for.

Floair Inhaler is for oral inhalation only.

It is important that even if you feel that your chest condition has improved, that you do not discontinue using your Floair Inhaler unless your doctor instructs you to.

The usual doses of Floair Inhaler are:

Adults and adolescents aged 16 years or older

The recommended dose is between 100 mcg to 1000 mcg twice a day (taken in the morning and evening).

Children aged 4 to 15 years

The recommended dose is between 50 mcg to 200 mcg twice a day (taken in the morning and evening).

Children aged less than 4 years

The recommended dose is 100 mcg twice a day (taken in the morning and evening), breathed in through a spacer device fitted with a facemask.

While you are using your Floair Inhaler

In the event of an asthma attack, use your “reliever” inhaler (e.g. salbutamol), not your Floair Inhaler.

Contact your doctor immediately if:

- Your breathing suddenly becomes more difficult just after you have used your Floair Inhaler;
- The effects of your Floair Inhaler does not continue as long as normal or does not assist your breathing the same as usual;
- Your asthma symptoms do not get better, or get worse, after seven days of using Floair Inhaler.

If you start taking any other medicine while you are using Floair Inhaler, tell your doctor or pharmacist.

If you have not used your Floair Inhaler as exactly as your doctor has prescribed, advise them of this information. If you do not, your doctor may change your

medication unreasonably under the impression that the medicine is not working for you.

Do not change the dosage or stop using your Floair Inhaler under any circumstances unless you have approval from your doctor.

All health providers should be informed that you are using your Floair Inhaler due to the steroids in your medication. You may require additional steroids (tablets or injections) at times when your body is stressed, for example, an accident, serious infection or if you are having an operation.

It is advised that if you have been prescribed Floair Inhaler along with steroid tablets that you should carry a steroid warning card with you in the event that extra oral steroids are required during times of stress.

If you forget to use your Floair Inhaler

If you have forgotten to take your normal dose at the correct time, take your next dose as soon as you remember. However, if you forget to take your Floair Inhaler close to the time of the next dose then simply miss out the dose you have forgotten.

Do not take a double dose of Floair Inhaler at any given time if you have missed a dose.

If you have difficulty remembering when the next dose of your inhaler is due, talk to your pharmacist for advice.

If you experience tightness in your chest or you become wheezy before you are due for the next dose, use your reliever inhaler (e.g. Salbutamol) as normal.

If you use too much of your Floair Inhaler (overdose)

If you or someone else takes too much of your Floair Inhaler, immediately phone the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or your doctor, even if you do not feel unwell or there are no signs of overdose symptoms.

Side effects

If you experience any of the following side effects, stop taking your Floair Inhaler and seek immediate medical attention as you may be allergic to the medicine:

- Itching, rash or reddened skin;
- Swelling of the eye lids, lips, face or throat;
- Low blood pressure causing you to feel weak or dizzy;
- Collapse;
- Increase in wheezing and shortness of breath immediately after using your inhaler.

If you experience any of the below side effects advise your nurse, pharmacist or doctor but do not discontinue using your Floair Inhaler.

Other side effects include:

- Headache;
- Dizziness;
- An increase in the amount of sugar in your blood;
- Thrush or other fungal infections in the mouth and throat. This can result in a sore tongue or throat;
- Inflammation of the sinuses (sinusitis);
- Muscle spasms;
- Coughing or shortness of breath;
- Diarrhoea;
- Indigestion;
- Agitation;
- Itchy skin;
- Sleeping problems, depression or feeling worried, aggression, anxiety, restlessness, nervousness, over-excitement or irritability. These effects are more likely to occur in children;
- Muscle pain;
- changes in bone mineral density (thinning of the bones);
- cataracts (clouding of the lens in the eye);
- glaucoma (increased pressure in the eye);
- slowing of the rate of growth of children and adolescents;
- round (moon shaped) face;
- urinary infections;
- painful oesophagus.

If steroids are taken over a long time and at high doses it can result in your adrenal glands being affected as they make their own steroid for the body. Tests may be conducted by your doctor to see how your adrenal glands are functioning. Please discuss any concerns with your doctor.

Floair Inhaler contains medication that is not addictive.

After using your Floair Inhaler

Storage and disposal

Keep out of reach of children by storing your Floair Inhaler in a locked cabinet at a height that is hard to reach for children.

Store Floair Inhaler below 25°C.

The shelf life of Floair Inhaler is 24 months.

Do not use after the expiry date. The expiry date can be found on the label on the canister and on the bottom of the carton.

When the Floair Inhaler is not in use, the plastic dust cap should be securely placed back on the mouthpiece of the actuator.

Avoid direct sunlight or heat. Do not store your Floair Inhaler in your car on a hot day or on a window sill. Protect your Floair Inhaler from frost.

As with other medication inhaled from aerosol canisters, the effect of the medication may be reduced if the canister is very cold. If this is the case, warm the inhaler in your hands for a few minutes before use. Do not use anything else to assist with warming up the inhaler.

Disposal

If your doctor advises you to stop taking Floair Inhaler, or it has exceeded its expiry date, request information from your pharmacist on what to do with any product that is left over.

As the canister is pressurised, no attempt should be made to puncture, or dispose of it by burning.

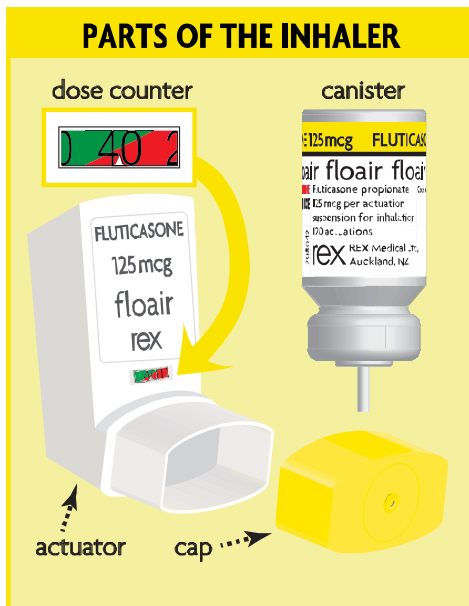
Product Description

What it looks like

Your Floair Inhaler contains a white plastic actuator that holds a metal canister with a white and yellow label. The canister is filled with your medication. The white plastic actuator has the name of your medication embossed on the front along with the name of the molecule of your medication and the strength you have been prescribed. The plastic dust cap is one of three shades of yellow indicating the strength.

Instructions for Use

Correct operation of the Floair Inhaler is essential for successful therapy.



All strengths of Floair Inhaler have the same instructions for handling, use and cleaning.

Prior to using the Floair Inhaler for the first time, remove the plastic dust cap from the mouthpiece of the inhaler, shake inhaler well and depress the canister twice into the air to prime the inhaler.



If the inhaler has not been used for more than one week, remove the plastic dust cap from the mouthpiece of the inhaler, shake the inhaler well and depress the canister once into the air to prime the inhaler.



Technique for proper administration of the Floair Inhaler is described in the following steps:

1. **Remove the plastic dust cap from the mouthpiece of the inhaler and check the mouthpiece is clean.** Shake inhaler well and prime if necessary.
2. **Hold the inhaler, using either one or two fingers on the top of the canister and your thumb on the base.** Breathe out deeply through your mouth. Place the mouthpiece of the actuator in your mouth taking care to not bite it and close your lips over the mouthpiece.



3. **Start breathing in through your mouth.** Then depress the canister to release one dose while continuing to breathe in deeply and steadily.
4. **Remove the inhaler from your mouth and hold your breath for 10 seconds or as long as comfortable.** Breathe out slowly.
5. **If another dose is required, wait for at least one minute with the inhaler in an upright position, and then repeat steps 2 to 4.**
6. **Rinse your mouth with water after inhalation and spit it out.**
7. **After use, replace the mouthpiece cover, making sure the dust cap is secure.**

IMPORTANT:

Do not rush steps 2, 3 and 4. It is essential that just before depressing the canister that you begin breathing in as slow as possible.

It is useful to complete this exercise using a mirror for the initial few actuations. If you see “mist or vapour” coming from the sides of your mouth or top of the inhaler, start again from step 2.

Make sure that you are operating your Floair Inhaler correctly with your pharmacist or doctor on a regular basis. Floair Inhaler may not work as well as it should if the technique you are using is not correct.

Provide feedback to your doctor if you have any concerns or issues when using your Floair Inhaler. If different directions have been provided by your doctor, please follow these instructions with care.

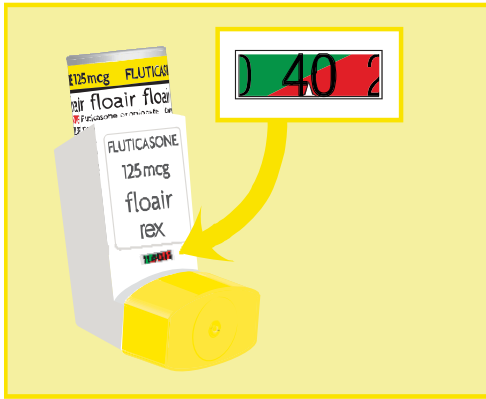
Have a spare Floair Inhaler available at all times.

Built-in Dose Counter

The Floair Inhaler has a built-in dose counter to see how many actuations are left in the inhaler.

After Floair Inhaler is primed for the first time, the dose counter should read 120. This means that there are 120 doses of medicine left in the inhaler. Each time the inhaler is used, the dose counter will count down by one number.

When there are 40 doses of medicine remaining in the Floair Inhaler, the colour on the dose counter will change from green to red.



When the dose counter on the Floair Inhaler is red, the patient should ask their doctor for a new inhaler.

The dose counter will stop counting when it reaches 0. This means that there is no medication left in the inhaler and it should be discarded.

The Floair Inhaler may not feel empty and may continue to operate; however, the right amount of medicine may not be dispersed if the inhaler is continued to be used once the dose counter has reached 0. The dose counter will continue to show 0 even if the inhaler is used again.

The dose counter cannot be reset and is permanently attached to the plastic actuator. Never try to change the numbers on the dose counter.

Cleaning

The Floair Inhaler plastic actuator should be cleaned at least once a week to ensure that it functions correctly.

NEVER wash or soak any part of the inhaler in water.



Use the following technique to clean your inhaler:

1. Remove the plastic dust cap from the mouthpiece of the inhaler. The metal canister should NOT be removed from the plastic actuator.



2. The plastic mouthpiece and the dust cap are to be wiped inside and outside with a clean dry cloth.
3. Replace the plastic dust cap on to the mouthpiece of the inhaler.

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