FLUTIFORM® INHALER

Fluticasone propionate/ formoterol fumarate dihydrate

Flutiform® 50 microgram /5 microgram, per actuation pressurised inhalation, suspension
Flutiform® 125 microgram /5 microgram per actuation pressurised inhalation, suspension
Flutiform® 250 microgram /10 microgram per actuation pressurised inhalation, suspension

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet

1. What ***Flutiform***® inhaler is and what it is used for
2. How ***Flutiform***® inhaler works
3. Before you use ***Flutiform***® inhaler
4. How to use ***Flutiform***® inhaler
5.While you are using ***Flutiform***® inhaler
6. Possible side effects
7.Storage and disposal of ***Flutiform***® inhaler
8. Product description
9. Manufacturer
10.Marketing Authorization Holder
11. Date of revision

What *Flutiform*® inhaler is and what it is used for

Please note:- ***Flutiform***® pressurized inhalation, suspension is the product name, however throughout this leaflet it is shortened to ***Flutiform***® Inhaler. Sometimes this may refer to a specific strength.

Flutiform® is an inhaler (a pressurized inhalation, suspension) which contains two active ingredients; fluticasone propionate and formoterol fumarate dihydrate.

This medicine helps to prevent breathing problems such as asthma and helps to stop you becoming breathless and wheezy. However, it does not work if you are already having an asthma attack i.e. you are already breathless and wheezing. You will need to use a fast acting 'reliever' medicine such as salbutamol if this happens.

How *Flutiform*® inhaler works

Flutiform® is an inhaler (a pressurized inhalation, suspension) which contains two active ingredients:

Fluticasone propionate which belongs to a group of medicines called steroids. Steroids help to reduce swelling and inflammation in the lungs.

Formoterol fumarate dihydrate which belongs to a group of medicines called long-acting beta$_2$ agonists. These are bronchodilators which help the airways in your lungs to stay open, making it easier for you to breathe. Together these two active ingredients help to improve your breathing. It is advised that you should use this medicine every day as directed by your doctor.

Before you use *Flutiform*® inhaler

When you must not use it

Do not use *Flutiform*® Inhaler if you:

- are allergic (hypersensitive) to fluticasone propionate, formoterol fumarate or any of the other ingredients (see section 8 'Product Description').

Before you start to use it

Before treatment with this inhaler, tell your doctor if you have:

- have tuberculosis (TB) now or in the past. Symptoms include a persistent cough often with blood streaked phlegm, fever, tiredness, loss of appetite, loss of weight and night sweats;
- have an infection of the lungs or chest;
- have heart problems such as problems with the blood flow to your heart or narrowing of one of your heart valves (the aortic valve), heart failure which can cause shortness of breath or ankle swelling, a condition where the heart muscle is enlarged (hypertrophic obstructive cardiomyopathy), an irregular heart beat (cardiac arrhythmias) or if you have been told that your heart trace is abnormal (prolongation of the QTc interval);
- have an abnormal bulging of a blood vessel wall (an aneurysm);
- have diabetes;
- have high blood pressure;
- have an overactive thyroid gland which can cause increased appetite, weight loss or sweating (thyrotoxicosis);
- have low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm (hypokalaemia);
- have poor adrenal gland function (if your adrenal gland is not working properly you may have symptoms such as headaches, weakness, tiredness, abdominal pain, loss of appetite, weight loss, dizziness, very low blood pressure, diarrhoea, feeling or being sick or fits) or a tumor of the adrenal gland (phaeochromocytoma);
- have liver problems.

If you are going to have an operation or are extremely stressed, please tell your doctor as you may need additional steroid treatment to control your asthma.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including other medicines and inhalers for asthma and medicines obtained without a prescription. If you use this inhaler with some other medicines the effect of this inhaler or the other medicine may be altered.

Tell your doctor or pharmacist if you are taking:

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- medicines known as beta-blockers (such as atenolol to treat blood pressure, sotalol to treat an irregular heart beat, metoprolol to treat a fast heart beat or timolol eye drops to treat glaucoma);
- certain other medicines used to treat asthma or breathing conditions (such as theophylline or aminophylline);
- medicines containing adrenaline or related substances (including other beta-agonists like salbutamol or betaantagonists including atenolol, metoprolol, propranolol, timolol). Additional long-acting beta$_2$ agonists should not be used together with this inhaler. If your asthma becomes worse between doses of ***Flutiform***® inhaler then you should use your quick acting 'reliever' inhaler for immediate relief;
- medicines to treat allergic reactions (antihistamines);
- medicines to treat high blood pressure or fluid build-up by increasing the amount of urine produced (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 (for example phenelzine and isocarboxazid), tricyclic antidepressants (for example amitriptyline and imipramine), 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 ketaconazole or itraconazole);
- medicines used to treat viral infections including HIV (for example ritonavir, atazanavir, indinavir, nelfinavir or saquinavir, cobicistat);
- antibiotics (such as clarithromycin, telithromycin or furazolidone);
- medicine to treat Parkinson's disease (levodopa);
- medicine to treat an underactive thyroid gland (levothyroxine);
- medicine to treat Hodgkin's disease (procarbazine);
- medicine to induce labour (oxytocin).

How to use *Flutiform*® inhaler

How much to take

Always use this inhaler exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. You should use your inhaler regularly i.e. two actuations (puffs) in the morning and two actuations (puffs) in the evening every day to get the most benefit from your inhaler, unless your doctor tells you otherwise or advises you to stop. Do not take more than the prescribed dose. Your doctor may have prescribed your inhaler for a different indication other than asthma/or at a different dose from that normally prescribed and as described in this leaflet. You should always use your inhaler exactly as your doctor has advised. If you are not sure about how much to take to use your inhaler please check with your doctor or pharmacist.

When to take it

Recommended dose for adults, adolescents and children aged 5 years and above:

The usual dose is two inhalations twice a day, that is two puffs (actuations) in the morning and two in the evening. Your doctor will prescribe the dose required to treat your asthma. **Only adults should use the highest strength inhaler (*Flutiform*® inhaler 250 microgram /10 microgram).**

Only adults and adolescents over 12 years of age should use the medium strength inhaler *Flutiform*® inhaler 125 microgram /5 microgram).

***Flutiform*® inhaler should not be used in children under 5 years of age.**

How long to take it

You should always use your inhaler exactly as your doctor has advised. If you are not sure about how often to use your inhaler please check with your doctor or pharmacist**.**

Instructions for use

Read this leaflet very carefully prior to use and follow the instructions for use in the text and diagrams below. Your doctor or pharmacist will show you how to use your inhaler properly. The medicine is contained in an aerosol can (see Diagram 1) which sits inside a plastic dispenser (also known as an actuator). The actuator also has a counter to tell you how many puffs (actuations) are left after it has been primed. When this is getting near to zero, you should contact your doctor for a replacement inhaler. Do not use your inhaler when the counter reads zero.

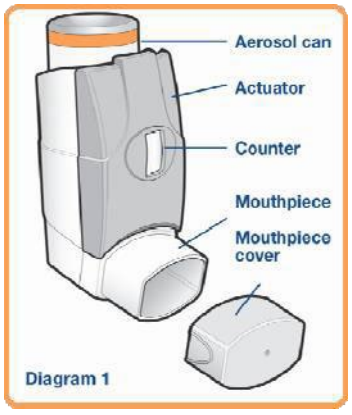


Diagram 1

Before you use your inhaler for the first time or if it hasn't been used for more than 3 days or if it has been exposed to freezing conditions

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If your inhaler is new or it hasn't been used for more than 3 days then it must be 'primed' to ensure it works properly and gives you the correct dose.

If your inhaler has been exposed to freezing temperatures it must be allowed to warm at room temperature for 30 minutes then it must be 'primed' to ensure it works properly and gives you the correct dose.

To prime the inhaler

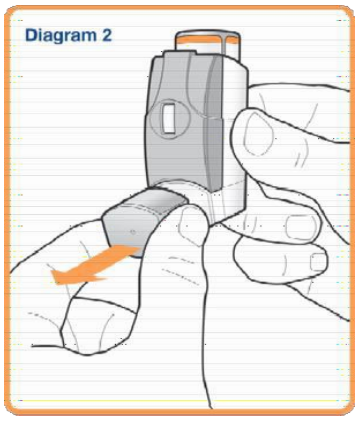
- Remove the mouthpiece cover and shake the inhaler well.
- Point the mouthpiece away from you and release one puff (actuation) by pressing down on the aerosol can. This step should be performed 4 times.

Your inhaler should always be shaken immediately before use.

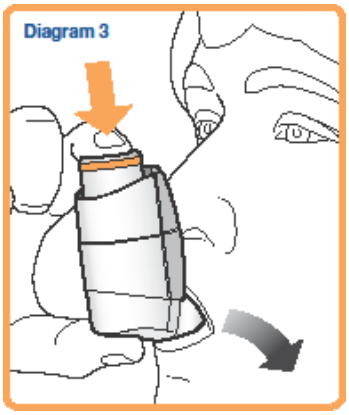
Using your inhaler

If you feel you are getting breathless or wheezy while using ***Flutiform***® inhaler, you should continue to use ***Flutiform***® inhaler but go to see your doctor as soon as possible, as you may need additional treatment. Once your asthma is well controlled your doctor may consider it appropriate to gradually reduce the dose of ***Flutiform***® inhaler.

Perform steps 2 to 5 below, slowly.



1. Remove the mouthpiece cover (see Diagram 2) and check that your inhaler is clean and free from any dust. The inhaler should be shaken immediately before releasing each puff (actuation).
2. Sit upright or stand. Breathe out as far as is comfortable and as slowly and as deeply as possible.



3. Hold your inhaler upright (as shown in Diagram 3) and put the mouthpiece in your mouth with your lips around it. Hold the inhaler with your thumb(s) on the base of the mouthpiece and forefinger/index finger(s) on the top of the inhaler. Do not bite the mouthpiece.
4. Breathe in slowly and deeply through your mouth and, at the same time, press down on the aerosol can to release one puff (actuation). Continue to breathe in steadily and deeply.



5. Continue to hold your breath for as long as is comfortable (ideally about 10 seconds). Finally, remove the inhaler from your mouth and breathe out slowly. Do not breathe out into the inhaler.
6. Keep the inhaler in a vertical position for about half a minute and then shake the inhaler prior to slowly repeating steps 2 to 5.
7. Replace the mouthpiece cover

You can practise in front of a mirror. If you see a 'mist' from the top of the inhaler or around your mouth when you use your inhaler then you may not have inhaled your medicine properly. Take another dose by repeating from Step 2 above.
Always rinse your mouth out, gargle with water or brush your teeth after you have taken your inhaler and spit out the residue. This may help prevent you developing a sore mouth and throat or a hoarse voice.

If you have difficulty using your inhaler your doctor may give you a spacing device, to help you to breathe your medicine into your lungs properly. Your doctor or pharmacist will advise you how to use the spacing device with your inhaler. The spacing device will come with instructions for use and with care and cleaning instructions which you must read carefully.

Caring for your inhaler

It is important that you follow these instructions carefully and clean your inhaler weekly. To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the aerosol can from the actuator.
- Wipe the inside and outside of the mouthpiece and the actuator with a clean, dry cloth or tissue.
- Replace the mouthpiece cover.
- Do not put the metal canister into water.

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If you forget to use *Flutiform*® inhaler
If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you use more Flutiform® inhaler than you should
It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.
If you take more of your medicine than you should, contact your doctor or pharmacist for advice. You may suffer from severe chest pain (angina), high or low blood pressure, a headache, muscle cramps, difficulty in sleeping, nervousness, a dry mouth, a loss of appetite, seizures, fits or convulsions.
You may feel shaky, light headed, faint, tired, sick or generally unwell. You may also notice changes in the rate of your heart beat and your blood may have low levels of potassium or an increase in the amount of sugar in your blood. You may also suffer from symptoms such as abdominal pain, being sick, weight loss, decreased level of consciousness (which could make you feel drowsy or confused) or a low blood sugar level.
If you have taken more than the prescribed dose for a long period of time, you should talk to your doctor or pharmacist for advice. This is because large doses may reduce the amount of steroid hormones produced normally by your adrenal glands (see section 8 'Product Description').

While you are using *Flutiform*® inhaler
Things you must do
Use your inhaler exactly as your doctor has advised.
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 you think you may be pregnant, planning to become pregnant or are breastfeeding talk to your doctor about using your inhaler. Your doctor will advise you if you should take this medicine.

Things you must not do
Do not give your inhaler to anyone else, even if they have the same condition as you.

Things to be careful of
Important information about some of the ingredients of *Flutiform*® inhaler
This medicine contains small amounts of ethanol (alcohol), i.e 1.00 mg per actuation (puff). It also contains a very small amount of sodium cromoglicate however patients who are currently taking cromoglicate (used to treat asthma, allergic rhinitis and allergic conjunctivitis) should continue as normal.

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

Possible Side Effects
Like all medicines, this inhaler can cause side effects, although not everybody gets them. Your doctor will prescribe the lowest dose necessary to control your asthma which may reduce the possibility of side effects occuring.

All medicines can cause allergic reactions.Tell your doctor immediately if you get any sudden swelling of the eyelids, face, throat, tongue or lips, rash or itching especially those covering your whole body, symptoms such as dizziness, light-headedness or fainting or any sudden changes in your breathing pattern such as increased wheezing or shortness of breath.

As with other inhalers, your breathing may worsen immediately after using your inhaler. If this happens stop using your ***Flutiform***® inhaler and use your quick acting 'reliever' inhaler. Contact your doctor straight away. He/She will assess you and may start you on a different course of treatment. You should carry your 'reliever' inhaler with you at all times.

Uncommon side effects (probably affecting less than 1 in 100 people using this inhaler)
- Worsening of asthma.
- An irregular heartbeat or palpitations

Rare side effects (probably affecting less than 1 in 1000 people using this inhaler)
- An increase in the amount of sugar in your blood. If you are diabetic you may need to check your blood sugar more often. Your doctor may need to monitor you more closely.
- Thrush, a fungal infection in the mouth and throat.
- Inflammation of the sinuses (sinusitis).
- Fast heartbeat.

Inhaled steroids can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time. The effects include:
- changes in bone mineral density (thinning of the bones);
- cataracts (clouding of the lens in the eye);
- glaucoma (increased pressure in the eye);
- bruising or thinning of the skin;
- slowing of the rate of growth of children and adolescents;
- a round (moon shaped) face;

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- weakness, tiredness, difficulty in coping with stress, abdominal pain, loss of appetite, weight loss.

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 [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Flutiform*® inhaler

Storage

Keep out of the reach and sight of children. Do not use this inhaler after the expiry date which is stated on the label, foil pouch and carton after EXP.

Store below 30°C. Do not refrigerate or freeze. Do not use the inhaler if it has been removed from the foil pouch for more than 3 months, or if the dose indicator reads '0'.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

What it looks like

These inhalers are small aerosol cans containing a white to off white liquid suspension fitted with a metering valve.

The aerosol cans are inserted into grey and white plastic dispensers (actuators) with a light grey mouthpiece cover. Each inhaler contains 120 puffs (actuations).

Ingredients

The active substances are fluticasone propionate and formoterol fumarate dihydrate.

The other ingredients are:

- Sodium cromoglicate
- Ethanol
- Apaflurane HFA 227 (propellant)

MAL No.

Flutiform® 50 mcg /5 mcg– MAL14125085ACZ

Flutiform® 125 mcg/5 mcg– MAL14125107ACZ

Flutiform® 250mcg /10 mcg- MAL14125108ACZ

Manufacturer

Recipharm HC Limited
London Road, Holmes Chapel, Crewe, Cheshire CW4 8BE United Kingdom.

Product Registration Holder

Mundipharma Pharmaceuticals Sdn Bhd
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No.12, Jalan PJU 7/5, Mutiara Damansara
47800 Petaling Jaya, Selangor,
Malaysia

Date of Revision

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