

**Patient Leaflet According to  
the Pharmacists' Regulations  
(Preparations) - 1986**

This medicine is sold only with  
a doctor's prescription

**Flutiform® 50/5**

**Flutiform® 125/5**

**Flutiform® 250/10**

**Suspension for Inhalation**

**Active ingredients:**

Each inhalation of **Flutiform 50/5** contains:  
50 mcg fluticasone propionate and 5 mcg formoterol fumarate dihydrate.

Each inhalation of **Flutiform 125/5** contains:  
125 mcg fluticasone propionate and 5 mcg formoterol fumarate dihydrate.

Each inhalation of **Flutiform 250/10** contains:  
250 mcg fluticasone propionate and 10 mcg formoterol fumarate dihydrate.

For list of inactive ingredients, please see section 6.

See also 'Important information about some of the medicine's ingredients' in section 2.

**Read this entire leaflet carefully before using this medicine.**

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

Flutiform 50/5 is not intended for use in children under 12 years of age.

Flutiform 125/5 is not intended for use in children under 12 years of age.

Flutiform 250/10 is not intended for use in children and adolescents under 18 years of age.

**1. What is this medicine intended for?**

The medicine is intended for treatment of asthma patients, in cases where a combined inhalation treatment of corticosteroid and long-acting beta-agonist is suitable.

Fluticasone propionate helps reduce swelling and inflammation in the lungs.

Formoterol fumarate dihydrate is a long-acting bronchodilator that helps keep the airways to the lungs open and eases breathing.

**Therapeutic groups:**

Fluticasone propionate: corticosteroids.

Formoterol fumarate dihydrate: beta-agonist (long-acting).

**2. Before you use the medicine**

**Do not use the medicine if:**

Do not use if you are sensitive (allergic) to the active ingredients or to any of the other ingredients of this medicine (for list of inactive ingredients, please see section 6).

**Special warnings regarding the use of this medicine:**

- If you are going to have an **operation**, or are **extremely stressed**, please inform your doctor, as you may need additional steroid treatment.
- Flutiform is not intended for treatment of a sudden asthma attack. An inhaler intended for the immediate relief of asthma attacks must be kept at hand.

**Before treatment with Flutiform tell the doctor if you suffer or have suffered in the past, from the following conditions:**

- Tuberculosis.
- An infection of the respiratory passageways (viral, fungal or other).
- 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 and ankle swelling), a condition where the heart muscle is enlarged, irregular heartbeats, or if you have been told that your heart trace is abnormal (prolongation of the QTc interval).
- Abnormal dilatation of a blood vessel wall (an aneurysm).
- Diabetes.
- High blood pressure.
- An overactive thyroid gland.
- Low blood levels of potassium.
- Impaired adrenal gland function (including a situation in which it was damaged due to steroid treatment) or a tumor of the adrenal gland.
- Liver problems.

**Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements.** In particular, inform your doctor or pharmacist if you are taking any of the following medicines (please note that the following list states the active ingredients in the medicines. If you are not sure whether you are taking one of these medicines, please consult your doctor or pharmacist):

- Medicines of the beta-blockers group such as: atenolol, propranolol, sotalol or metoprolol (to treat heart and blood vessels problems), timolol (found, for example, in eye-drops for glaucoma treatment).
- Certain medicines used to treat asthma and breathing problems such as: theophylline or aminophylline.
- Medicines containing adrenaline or similar substances (including other beta-agonist medicines like salbutamol): additional long-acting beta agonist medicines should not be used together with this inhaler. If your asthma worsens between one dose of Flutiform to the next, use your inhaler intended for immediate relief of asthma attacks.
- Antihistamines (for allergy treatment).
- Diuretics (for the treatment of high blood pressure or fluid accumulation).
- Medicines for the treatment of heart problems such as: digoxin, quinidine, disopyramide, procainamide.
- Medicines to treat mental disorders or depression such as: tricyclic antidepressants (e.g. amitriptyline, imipramine), monoamine oxidase inhibitors (e.g. phenelzine, isocarboxazid). Inform your doctor even if you have taken these medicines within the past two weeks.
- Medicines to treat psychiatric disorders (such as phenothiazines, antipsychotic medicines).
- Other medicines containing steroids.

- Antifungal medicines such as: ketoconazole, itraconazole.
- Medicines for the treatment of viral infections (including for the treatment of AIDS) such as: ritonavir, atazanavir, indinavir, nelfinavir, saquinavir.
- Antibiotics such as: clarithromycin, telithromycin, furazolidone.
- Levodopa (for the treatment of Parkinson's disease), levothyroxine (for the treatment of an underactive thyroid gland), oxytocin (for labour induction).
- Procarbazine (for the treatment of Hodgkin's disease).
- Anaesthetics (used in operations).

**Use of this medicine and alcohol consumption:** consult the doctor.

**Pregnancy and breastfeeding:**

If you are pregnant, planning to become pregnant or are breastfeeding consult your doctor before using this medicine.

**Important information about some of the medicine's ingredients:**

- Flutiform contains small amounts (1 mg per inhalation) of ethanol (alcohol).
- Flutiform contains a small amount of sodium cromoglicate. If you are using another medicine containing sodium cromoglicate, you may continue using it as usual.

**Use in children:**

- Flutiform 50/5 is not intended for use in children under 12 years of age.
- Flutiform 125/5 is not intended for use in children under 12 years of age.
- Flutiform 250/10 is not intended for use in children and adolescents under 18 years of age.

**3. How to use this medicine?**

Always use according to the doctor's instructions. If you are not sure, check with your doctor or pharmacist. The dosage and manner of treatment will be determined by the doctor only.

**The standard dosage for adults and adolescents over 12 years of age is usually:** two puffs (inhalations) in the morning and two puffs in the evening.

The highest dose of Flutiform (Flutiform 250/10) is not intended for use in adolescents under 18 years of age.

**Do not exceed the recommended dose.**

**Attention!** This medicine is intended for inhalation only!

**Instructions for use:**

The medicine is contained in an aerosol can, which sits inside a plastic cover (the inhaler). The inhaler has a dosage counter which indicates how many doses remain in the inhaler. When the dosage counter approaches zero, refer to your doctor to get a prescription for a new inhaler. Do not use the inhaler when the dosage counter indicates zero.

**Preparing the inhaler:**

- Before using the inhaler for the first time, or if the inhaler hasn't been used for more than 3 days, it should be primed to ensure it works properly and dispenses the correct dose.
- If the inhaler has been exposed to freezing temperatures, it must be allowed to warm up at room temperature for 30 minutes, and then primed, to ensure it works properly and dispenses the correct dose.

To prime the inhaler:

- Remove the mouthpiece cover and shake the inhaler well.
- Point the mouthpiece away from you and release 4 puffs (actuations) into the air, by pressing down on the medicine's aerosol can.

**Using the inhaler:**

If you feel you are getting wheezy or breathless while using the inhaler, continue its use and refer to your doctor as soon as possible.

The following steps should be performed, while making sure steps 2 through 5 are performed slowly:

1. Remove the mouthpiece cover and check that the inhaler is clean and free from dust. The inhaler must be shaken immediately before releasing each measured amount for inhalation.
2. Sit upright or stand. Breathe out as slowly and deeply as possible.
3. Hold the inhaler in an upright position, with your thumb on the base of the inhaler, under the mouthpiece, and your index finger on top of the inhaler. Insert the mouthpiece into your mouth tightening your lips around it. Do not bite the mouthpiece (see illustration).
4. Breathe in slowly and deeply through your mouth and, at the same time, press down on the medicine's aerosol can to release one measured amount for inhalation. Continue breathing in deeply.
5. Continue to hold your breath as long as you can (ideally for about 10 seconds). Remove the inhaler from your mouth and breathe out slowly. Do not breathe out into the inhaler.
6. Hold the inhaler in an upright 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 practice the use in front of a mirror.

If you see a "mist" over the inhaler or around your mouth while using the inhaler, you may not have inhaled your medicine properly. Take another dose by repeating step 2 onwards.

- After using the inhaler, rinse your mouth out, gargle with water or brush your teeth. These actions may help reduce the risk of developing a fungal infection, sore mouth and throat or hoarseness.
- If you have weak hands it might be easier for you to hold the inhaler in both hands, placing both index fingers on the medicine's aerosol can and both thumbs on the base of the inhaler.
- If necessary, you can use a spacer (AeroChamber Plus).

**Cleaning the inhaler:**

The inhaler should be cleaned once a week. Follow the cleaning instructions carefully:

- Remove the mouthpiece cover. Do not remove the medicine's aerosol can from the plastic cover.
- Clean the inner and outer sides of the mouthpiece, as well as the plastic cover, with a clean, dry cloth or tissue.
- Replace the mouthpiece cover.
- The metal aerosol can should not come in contact with water.

**Tests and follow-up:**

- The doctor will follow-up on your asthma symptoms and your reaction to the treatment.
- In diabetics – a closer follow-up might be required.
- In certain cases the doctor might check your blood potassium levels.
- In children over 12 years of age using the medicine for long periods – a growth follow-up is recommended.

**If you have taken an overdose or if a child has accidentally swallowed the medicine**, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If sever overdose symptoms appear, proceed immediately to get medical assistance. Overdose symptoms include: sever chest pain, high or low blood

pressure, headache, muscle cramps, difficulty sleeping, nervousness, dry mouth, loss of appetite, convulsions, seizures, tremor, dizziness, fainting, tiredness, feeling sick or generally unwell. Also possible are heartbeat rate irregularities, decreased potassium levels, increase or decrease in blood sugar levels, abdominal pain, nausea, vomiting, weight loss, decreased level of consciousness (which can be manifested by confusion and sleepiness).

If you have used a higher dose than recommended for a long period of time, consult your doctor, as high dosages may reduce the amount of steroid hormones normally produced by your body (see section 'side effects').

**If you forgot to use the inhaler** at the set time, use it as soon as you remember. If it is time for your next dose, skip the missed dose. Do not take two doses to make up for a forgotten dose.

You should follow the treatment course as recommended by your doctor.

Even if your state of health improves do not stop treatment with this medicine without consulting your doctor or pharmacist.

**If you stop taking your medicine:** it is very important that you use the inhaler every day, as instructed by your doctor, to control your asthma, even if you are feeling well. If you wish to stop using the inhaler, consult the doctor. The doctor will decide on the way to do it, usually by gradually decreasing the dose, in order to avoid triggering an asthma attack.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have additional questions regarding the use of the medicine, consult a doctor or pharmacist.

**4. Side effects**

Like all medicines, the use of Flutiform may cause side effects in some patients. If these side effects persist or are bothersome or get worse, consult your doctor. Do not be alarmed while reading the list of side effects. You may not suffer from any of them. Your doctor will prescribe the lowest dose necessary to treat your asthma, in order to reduce the chance for side effects.

**Refer to a doctor immediately** if an allergic reaction occurs. A severe allergic reaction is rare. Symptoms of an allergic reaction include: sudden swelling of the eyelids, face, throat, tongue or lips, rash or itching (especially those involving the entire body), dizziness, fainting, sudden change in breathing pattern (such as increased wheezing or shortness of breath).

**Stop using the inhaler** and refer to a doctor, if immediately after using Flutiform you sense increased wheezing and shortness of breath. In such a case, use the inhaler you have for situations where you need immediate relief, and refer to a doctor.

**Additional side effects:**

*Uncommon side effects (appear in less than 1 in 100 patients):*

- Increased blood sugar levels. If you are diabetic you may need to check your blood sugar more often and adjust your diabetic treatment. Your doctor might monitor you more often.
- Worsening of asthma.
- Headache, shaking, irregular or strong heartbeats (palpitations); dizziness; changes in taste sensation, voice alterations, hoarse voice; dry mouth, sore or irritated throat; swelling of hands, ankles or feet (edema).

*Rare side effects (appear in less than 1 in 1000 patients):*

- Fungal infection in the mouth and throat; inflammation of the sinuses (sinusitis); fast heartbeat; chest pain associated with heart disease; muscle spasms; coughing or shortness of breath; diarrhoea; indigestion; feeling dizzy (vertigo); abnormal dreams or difficulty sleeping; agitation; rash; high blood pressure; unusual weakness.

*Side effects of unknown frequency:*

- Sleeping problems, feeling worried or depressed, aggression, anxiety, restlessness, nervousness, overexcitement, irritability.
- The following effects are associated with the use of formoterol fumarate: decreased blood levels of potassium (which can cause muscle weakness, twitching, abnormal heart rhythm), QTc interval prolongation in heart trace, high blood levels of lactic acid, nausea, muscle pains.
- The use of inhaled steroids may affect the normal production of steroid hormones in your body, particularly if you use a high dose for a long time. The effects include: changes in bone density (thinning of the bones), cataract, glaucoma (increased pressure in the eye), bruising or thinning of the skin; an increased risk of catching an infection, slowed growth rate of children and adolescents, round face ("moon face"), an effect on the adrenal gland (a gland next to the kidneys) which causes: weakness, tiredness, difficulty in coping with stressful situations, abdominal pain, loss of appetite, weight loss, headache, dizziness, low blood pressure, diarrhoea, nausea, vomiting, seizures.

In any case you experience side effects that are not mentioned in this leaflet or if you feel a change in your general feeling, consult your doctor immediately!

**5. How to store the medicine?**

Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C. Do not refrigerate or freeze.
- If the inhaler is exposed to freezing temperatures, it must be allowed to warm up at room temperature for 30 minutes, and primed before use (see section 3 'How to use this medicine').
- Do not use for more than 3 months after removing the inhaler from the foil pouch, or if the dose counter indicates "0" (zero).
- Do not expose to temperatures exceeding 50°C. The medicine's aerosol can contains a pressurized liquid, therefore do not puncture, break or burn the can, even if it seems empty.

**6. Further information**

- **In addition to the active ingredients, this medicine also contains the following inactive ingredients:**  
Sodium cromoglicate, ethanol, hydrofluoroalkane (HFA 227)
- **What does the medicine look like and what does the package contain?**  
The inhaler includes the medicine's aerosol can, which contains a white suspension; fitted in a grey and white plastic cover. The mouthpiece cover is light grey.  
Each inhaler contains 120 puffs.  
Each package contains one inhaler.

**Registration holder:** Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301

**Manufacturer:** SkyePharma AG, MuttENZ, Switzerland

**Medicine registration number in the National Medicine Registry of the Ministry of Health:**

Flutiform 50/5: 150 62 33812

Flutiform 125/5: 150 63 33813

Flutiform 250/10: 150 64 33814

This leaflet was checked and approved by the Ministry of Health in August 2013.