

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed according to a physician's prescription only

Flixotide Inhaler CFC Free 50 mcg, Suspension for Inhalation

Each dose contains 50 micrograms of fluticasone propionate.

Flixotide Inhaler CFC Free 125 mcg, Suspension for Inhalation

Each dose contains 125 micrograms of fluticasone propionate.

Flixotide Inhaler CFC Free 250 mcg, Suspension for Inhalation

Each dose contains 250 micrograms of fluticasone propionate.

For the list of the inactive and allergenic ingredients in the medicine, see section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Flixotide Inhaler is used as a preventive treatment for asthma and for treatment and reduction of symptoms in chronic obstructive pulmonary disease (COPD) when used in combination with long acting bronchodilators.

Only the 250 mcg strength Flixotide Inhaler is suitable for the treatment of COPD.

In children aged 1-4 years: Flixotide Inhaler 50 mcg is beneficial in control of persistent asthma symptoms.

Therapeutic group:

Corticosteroids

Flixotide Inhaler contains fluticasone propionate, which belongs to a group of medicines called corticosteroids (a group of synthetic hormones, often called steroids). Flixotide

Inhaler works by reducing swelling and irritation in the lungs. It has an anti-inflammatory action. A very small dose is needed, as it is inhaled straight to the lungs.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in this medicine (as listed in section 6).

Special warnings regarding use of the medicine

Before the treatment with Flixotide Inhaler, tell the physician if:

- you have ever been treated for tuberculosis (TB)
- you have ever had thrush in your mouth
- you are using Flixotide Inhaler at the same time as taking steroid tablets. Also if you have just finished taking steroid tablets
- you have diabetes mellitus (Flixotide Inhaler may increase your blood sugar level)

If you are not sure if any of these apply to you, talk to your physician or pharmacist before using Flixotide Inhaler.

If you find that your medicine for treating sudden asthma attacks is not working as well as before, or you need to take it more than usual, refer to your physician.

If your breathing suddenly gets worse, this can be life-threatening, so seek medical advice urgently.

If your breathing or wheezing gets worse straight after using Flixotide Inhaler, **stop using it and tell your physician immediately.**

Contact your physician if you experience blurred vision or other visual disturbances, which may be caused by cataract or glaucoma.

Children and adolescents

Flixotide Inhaler at a dosage of 125 mcg and 250 mcg is not recommended for children under 16 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Remember to take this medicine with you if you have to go to the hospital.

In particular if you are taking any of the following:

- antiviral medicines known as a 'protease inhibitors' (such as ritonavir) or medicines that contain the active ingredient cobicistat, which may increase the effect of fluticasone propionate. Your physician may wish to monitor your condition carefully if you are taking these medicines.
- medicines used to treat fungal infections (such as ketoconazole).

If you are not sure if any of the above apply to you, talk to your physician or pharmacist before using Flixotide Inhaler.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician for advice before using this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

Flixotide Inhaler comes in three different dosages. You should not increase or decrease your dosage without seeking medical advice.

Using this medicine

- Instructions on how to use the inhaler are given at the end of the leaflet under 'Instructions for use'.
- Some people find it difficult to release a dose of medicine just after they start to breathe in. A spacer device helps to overcome this problem. Your physician or pharmacist will be able to advise you about this.
- **It may take a few days to a few months until this medicine starts to have an effect and it is very important that you use it regularly.** Do not stop treatment, even if you feel better, unless your physician tells you to stop.

The dosage and treatment regimen will be determined by the physician only. The recommended dosage is usually:

For asthma:

- Children 1-4 years of age: 50 to 100 mcg, twice daily.
- Children 4-16 years of age: 50 to 100 mcg, twice daily.
- Adults and children over 16 years of age: 100 to 1,000 mcg, twice daily.

Chronic Obstructive Pulmonary Disease (COPD):

Adults

- The usual dose is: 500 mcg twice daily, when used in combination with long acting bronchodilators.

Only the Flixotide Inhaler 250 mcg dosage is suitable for the treatment of COPD.

Do not exceed the recommended dose.

Flixotide Inhaler at a dosage of 125 and 250 mcg is not recommended for children below 16 years of age.

It is recommended that children being treated with steroids, including Flixotide Inhaler, have their height checked regularly by their physician.

Your physician may give you a Flixotide Inhaler of a higher strength if your dosage needs to be increased.

If you are using high dosages of inhaled steroids 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 physician may decide to give you extra steroid medicines during this time.

Patients who are taking high dosages of steroids, including Flixotide Inhaler, for a long time, must not stop taking their medicine suddenly without talking to their physician. Suddenly stopping treatment can make you feel unwell and may cause symptoms such as vomiting, drowsiness, nausea, headache, tiredness, loss of appetite, low blood sugar level and convulsions.

If you accidentally have taken a higher dosage

If you use more than you should, talk to your physician as soon as possible.

If you have taken an overdose or if a child has accidentally taken some medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine

If you forgot to take this medicine at the scheduled time, do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time and consult the physician.

Adhere to the treatment regimen recommended by your physician.

If you stop taking the medicine

Even if your health condition improves, **do not stop treatment** with the medicine, unless told to do so by your physician.

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 further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Flixotide Inhaler may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

If you notice any of the following serious side effects, stop using this medicine and talk to your physician straight away. You may need urgent medical treatment.

- allergic reactions (may affect up to 1 in 100 people) – the signs include skin rashes, redness, itching or wheals like nettle rash or hives.
- severe allergic reactions (may affect up to 1 in 10,000 people) – the signs include swelling of your face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint, light-headed and collapse.
- your breathing or wheezing gets worse straight after using your inhaler.

Pneumonia (infection of the lung) in COPD patients (common side effect)

Tell your physician if you have any of the following symptoms during the course of treatment with Flixotide Inhaler – these could be signs of a lung infection:

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties

Other side effects include:

Very common side effects

These may affect more than 1 in 10 people:

- thrush in the mouth and throat

Common side effects

These may affect up to 1 in 10 people:

- hoarseness of voice
- bruising

Side effects in your mouth and throat can be reduced by doing the following straight after inhaling the dose: brushing your teeth, rinsing your mouth or gargling with water and spitting it out. Tell your physician if you have problems with your mouth or throat, but do not stop treatment unless you are told to.

Rare side effects

These may affect up to 1 in 1,000 people:

- thrush (candidiasis) in the oesophagus

Very rare side effects

These may affect up to 1 in 10,000 people:

- sleeping problems or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children.
- level of sugar (glucose) in your blood may be increased.
- the way steroids are produced by your body may change during the course of treatment with Flixotide Inhaler (adrenal suppression). This is more likely to happen if you use high dosages for a long period of time (e.g., 400 micrograms daily in children). This can cause:

- children and young people to grow more slowly.
- 'Cushing's syndrome'. This happens when you have too much steroids in your body and it can cause thinning of your bones and eye problems (such as cataracts and glaucoma, which is high pressure in the eye).

Your physician will help stop this happening by making sure you use the lowest dose of steroids which controls your symptoms.

Side effects of unknown frequency (frequency was not yet determined), but may also occur

- depression or aggression. These effects are more likely to occur in children.
- nosebleeds.
- blurred vision (which may be due to cataract or glaucoma).

Talk to your physician as soon as possible if:

- after 7 days of treatment with Flixotide Inhaler your shortness of breath or wheezing does not get better or gets worse.
- you or your child use high doses of inhaled steroids and are feeling unwell with symptoms such as tummy ache, sickness, diarrhoea, headache or drowsiness. This can happen during an infection such as a viral infection or stomach upset. It is important that your steroid therapy is not stopped suddenly as this could make your asthma worse and could also cause problems with the body's hormones.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Clean your inhaler on a weekly basis, and if it becomes blocked, as described under 'Cleaning your Inhaler' in section 6 – "Additional information".
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 30°C.
- Do not refrigerate or freeze.
- Store in the original package.
- Protect from frost and direct sunlight.
- 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.
- The canister contains a pressurised liquid. Do not expose it to temperatures higher than 50°C. Do not puncture, break or burn it even when apparently empty.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains HFA-134a (also known as: GR106642X).
- What the medicine looks like and the contents of the package:
Flixotide Inhaler comprises an aluminium canister sealed with a metering valve, actuator and dust cap.
Each canister of 50 micrograms fluticasone propionate contains 120 doses.
Each canister of 125 or 250 micrograms fluticasone propionate contains 60 or 120 doses.
Not all pack sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Trading Services Limited, Dublin, Ireland.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Flixotide Inhaler 50 mcg: CFC Free 131-50-31008

Flixotide Inhaler 125 mcg: CFC Free 129-81-30973

Flixotide Inhaler 250 mcg: CFC Free 129-80-30974

Instructions for use

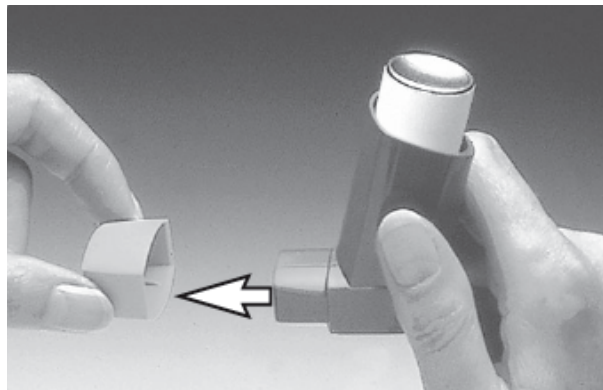
Your physician or pharmacist should show you how to use your inhaler. They should check from time to time if you are using the inhaler properly. Not using the Flixotide Inhaler properly or not using as prescribed for you may mean that the medicine will not help your asthma as it should.

The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece.

Testing your inhaler

1 When using the inhaler for the first time or if you have not used it for a week or more, test that it is working. 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 it well, point the mouthpiece away from you and press the canister to release two puffs into the air.



Using your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

1 Stand or sit upright when using your inhaler.

2 Remove the mouthpiece cover (as shown in the first picture). Check inside and outside to make sure that the mouthpiece is clean and free of objects.

3 Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.



4 Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable. Do not breathe in again yet.



5 Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.



6 Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a dose of medicine. Do this while still breathing in steadily and deeply.



7 Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.



8 If your physician has told you to take two doses, wait about half a minute before you take another dose by repeating steps 3 to 7.

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

10 After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position. Practise in front of a mirror for the first few times. If you see a 'mist' coming from the top of your inhaler or the sides of your mouth you should start again.

Some people find it difficult to release a dose of medicine just after they start to breathe in. You may find that a spacer device helps to overcome this problem – speak to your physician if you think you might need one of these. Young children may need help and their parents may need to operate the inhaler for them. Encourage the child to breathe out and operate the inhaler just after the child starts to breathe in. Practise the technique together.

If you have to give Flixotide Inhaler to a child under the age of 5, a special device designed for use with young children may make it easier – speak to your physician if you think you might need one of these.

Children and other people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece. If this does not help, a special device may make it easier. Your physician or pharmacist will be able to advise you.

Cleaning your Inhaler

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

To clean your inhaler:

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

Do not put the metal canister in water.

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