

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

The medicine is dispensed with a physician's prescription only

Flixotide Nebules 2 mg/2 ml, Inhalation Suspension for Nebulisation

Each 2 ml of Flixotide Nebules contain 2 mg fluticasone propionate.
A list of the additional ingredients is detailed in section 6.

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 the pharmacist.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

In adults and adolescents over 16 years of age: For prophylactic management of severe chronic asthma in patients requiring high dose inhaled or oral corticosteroid therapy.

Therapeutic group: corticosteroids

Fluticasone propionate belongs to a group of medicines called corticosteroids (sometimes just called steroids). When taking steroids by inhalation, a very low dosage is required since the medicine goes straight to the lungs.

Flixotide Nebules reduces swelling and irritation in the lungs, meaning, Flixotide Nebules has an anti-inflammatory effect.

When Flixotide Nebules is used as a prophylactic therapy, it is very important to adhere to a daily treatment regimen.

Flixotide Nebules is not intended to treat sudden asthma attacks, where you feel breathless. There are other medicines to treat sudden attacks. If you use more than one medicine concomitantly, be careful not to confuse them.

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 the medicine, as detailed in section 6.

Do not use Flixotide Nebules if the above applies to you.

If you are not sure, refer to your physician or pharmacist before using Flixotide Nebules.

Special warnings regarding the use of this medicine

Before beginning treatment with Flixotide Nebules, tell your physician or pharmacist if:

- You have ever been treated for tuberculosis (TB).
- You are using Flixotide Nebules at the same time as taking steroid tablets. Also, if you have just finished taking steroid tablets.

If you find that the medicine to treat your 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, it can be life-threatening; therefore, seek medical advice urgently.

Refer to your physician if you experience blurred vision or other visual disturbances.

If you are not sure if any of the above applies to you, refer to your physician or pharmacist before using Flixotide Nebules.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the physician or the pharmacist. In particular, inform the physician or the pharmacist if you are taking:

- A type of antiviral medicine known as a 'protease inhibitor' (such as ritonavir) or medicines containing cobicistat, which may lead to an increase in the effect of fluticasone propionate. Your physician may want to monitor you, if you are taking any of these medicines.
- Medicines used to treat fungal infections (such as ketoconazole).

If you are not sure if any of the above applies to you, refer to your physician or pharmacist before using Flixotide Nebules.

Children and adolescents

Flixotide Nebules 2 mg/2 ml is not intended for use in children under 16 years of age.

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

Use of the medicine and food

You can use Flixotide Nebules at any time of the day, with or without food.

Pregnancy, breast-feeding and fertility

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 taking this medicine.

Driving and using machinery

Flixotide Nebules is not likely to affect your ability to drive or use any tools or machines.

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 regarding the dosage and treatment regimen of the preparation.

Flixotide Nebules comes in two different strengths. Your physician will decide

which strength you need. The dosage and treatment regimen will be determined by a physician only.

The usual dosage for adults and adolescents over 16 years of age is generally:

- The usual starting dose is 0.5 mg to 2 mg (500 to 2,000 micrograms) twice a day.
- Each Nebule of Flixotide Nebules 0.5 mg/2 ml provides you with a dose of 500 micrograms.
- Each Nebule of Flixotide Nebules 2 mg/2 ml provides you with a dose of 2,000 micrograms.

Do not exceed the recommended dose.

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 have been treated with high dosages of steroids, including Flixotide Nebules, for a long time, must not stop taking their medicine suddenly without consulting with a 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 fitting.

Using the medicine

- **Do not inject or swallow the liquid.** The medicine should only be inhaled using a nebuliser. Using Flixotide Nebules with an ultrasonic nebuliser is not generally recommended.
- The nebuliser produces a fine mist which you inhale through a mouthpiece or face mask.
- **Do not let the liquid or the mist produced by the nebuliser get into your eyes.** You can wear glasses or goggles to protect them.
- Each small plastic container (Nebule) contains liquid.
- The liquid is put into the nebuliser. The device produces a fine mist for you to inhale through a mouthpiece or face mask. Use of a mouthpiece prevents the medicine from affecting the skin of your face, which may occur if you use a face mask over a long period of time. If you prefer to use a face mask, or you are using a face mask for your child, then you must protect the skin on your face (or the skin of your child's face) with a barrier cream or wash your (or your child's) face thoroughly after treatment.
- Use the nebuliser in a well-ventilated room as some of the mist will be released into the air and may be inhaled by others.
- **It takes a few days for this medicine to start working; therefore, it is very important that you use it regularly.**

Instructions for use

1. The Nebules are in an aluminum foil pack. Do not open the pack until you need to use them.
2. Shake the Nebule well before use. Hold the upper tip of the Nebule you have taken out. Twist the body of the Nebule to open it.



3. Put the open end of the Nebule into the designated spot in the nebuliser and slowly squeeze the Nebule to empty its contents.



4. Assemble the nebuliser and use it as directed.
5. Repeat steps 2 to 4 to make up the dosage needed, if necessary.

Diluting the Nebule

Do not dilute the contents of a Nebule unless you are told to do so by your physician

- If your physician has told you to dilute the solution, empty the contents of the Nebule into the nebuliser.
- Add the amount of sterile sodium chloride 0.9% solution your physician has told you to use.
- Close the cover and gently shake to mix the contents.

If dilution is necessary, then only sterile sodium chloride 0.9% solution should be used.

After use

- Use a fresh Nebule for each dose. Open a new Nebule only when you are ready to use it. If there is any liquid left over, throw it away. Do not save it to use again.
- Throw away any solution remaining in the nebuliser.
- Clean the nebuliser as recommended in the device's instructions for use.

If you accidentally took a higher dosage

If you took an overdose, or if a child has accidentally swallowed the medicine, **refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.** It is important that you take your dosage as stated on the pharmacist's label or as advised by your physician. Do not increase or decrease your dosage without consulting your physician.

If you forgot to take the medicine

- Take the next dose when it is due.
- Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment regimen recommended by the physician.

If you stop taking the medicine

Even if there is an improvement in your health, **do not stop treatment with the medicine** without consulting the 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 the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Flixotide Nebules 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 occur in up to 1 in 100 users) - the signs include skin rashes, redness, itching or weals like nettle rash (hives).
- Severe allergic reactions (may occur in up to 1 in 10,000 users) - the signs include swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint, lightheadedness and collapse.
- Your breathing or wheezing gets worse straight after using the medicine.

Additional side effects

Very common side effects (may occur in more than 1 in 10 users)

- Thrush in the mouth and throat

Common side effects (may occur in up to 1 in 10 users)

- Sore tongue or throat
- Hoarseness

Problems with your mouth and throat can be reduced by taking certain precautions right after inhalation. These are: brushing your teeth, rinsing your mouth or gargling with water and spitting it out. Tell your physician if you have these problems with your mouth or throat, but do not stop treatment unless you are told to.

The following side effects have also been reported in patients with chronic obstructive pulmonary disease (COPD):

- Pneumonia. Tell your physician if you notice any of the following symptoms: increased sputum production, change in sputum color, fever, chills, increased cough, increased breathing problems.
- Bruising.

Rare side effects (may occur in up to 1 in 1,000 users)

- Thrush (candidiasis) in the esophagus

Very rare side effects (may occur in up to 1 in 10,000 users)

- Sleeping problems or feeling worried, over-excited and irritable. These effects are more likely to occur in children
- Joint pains
- Indigestion

- Level of sugar (glucose) in your blood may be increased.
 - The way steroids are produced by your body may be affected when using Flixotide Nebules. This is more likely to happen if you use high dosages for a long period of time. This can cause:
 - Slowed growth in children and adolescents.
 - An effect called '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: cataract and glaucoma which is high pressure in the eye)
- Your physician will help stop onset of these effects by making sure you use the lowest dosage of steroids needed to control your symptoms.

Although their frequency is not known, the following side effects may also occur:

- Depression, feeling restless or nervous. These effects are more likely to occur in children
- Nosebleed
- Blurred vision.

Refer to the physician as soon as possible if:

- After 7 days of using Flixotide Nebules, your shortness of breath or wheezing does not get better, or gets worse.
- If you or your child is taking a high dosage of inhaled steroids and feels unwell with vague symptoms such as tummy ache, nausea, diarrhea, headache or drowsiness. This can happen during an infection such as a viral infection or stomach upset. It is important that your steroid treatment is not stopped suddenly as this could make your asthma worse and could also cause problems with the hormones in your body.

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

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 SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- 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 Flixotide Nebules in the aluminum foil wrap, inside the outer carton.
- Do not store above 30°C. Keep the Nebules in the outer carton in order to protect from light. Do not freeze. Store upright.
- Nebules removed from the aluminum foil wrap should be protected from light and used within 28 days.
- Use immediately after opening the Nebules. Discard if not used immediately.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
Monosodium phosphate dihydrate, sodium chloride, dibasic sodium phosphate anhydrous, polysorbate 20, sorbitan laurate, water for injection.
- What the medicine looks like and the contents of the package:
Flixotide Nebules is provided as a strip of 5 Nebules in an aluminum foil wrap. Each box contains 10 Flixotide Nebules.
- License Holder and Importer: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Australia PTY Ltd., Boronia, Australia.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 113-88-29614

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