

GSK logo

Package leaflet: Information for the user

Flixotide Nebules 0.5 mg/2 ml

fluticasone propionate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this section. See section 4.

What is in this leaflet:

- 1 What Flixotide is and what it is used for
- 2 What you need to know before you use Flixotide
- 3 How to use Flixotide
- 4 Possible side effects
- 5 How to store Flixotide
- 6 Contents of the pack and other information

1 What Flixotide is and what it is used for

Flixotide Nebules contain a medicine called fluticasone propionate.

Fluticasone propionate belongs to a group of medicines called corticosteroids (often just called steroids). A very small dose of steroid is needed when it is inhaled. This is because it is inhaled straight to your lungs.

Flixotide works by reducing swelling and irritation in the lungs. It has what is called an 'anti-inflammatory action'.

Flixotide help to prevent asthma attacks in people who need regular treatment. This is why they are sometimes called 'preventers'. They need to be used regularly, every day.

Flixotide will not help treat sudden asthma attacks where you feel breathless.

- A different medicine is used for treating sudden attacks (called a 'reliever').
- If you have more than one medicine, be careful not to confuse them.

2 What you need to know before you use Flixotide

Do not use:

- if you are allergic to fluticasone propionate or any of the other ingredients of this medicine (listed in Section 6).

Do not use Flixotide if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before using Flixotide.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Flixotide if:

- you have ever been treated for tuberculosis (TB)
- you are using Flixotide at the same time as taking steroid tablets. Also if you have just finished taking steroid tablets. In both cases, you should carry a steroid warning card until your doctor tells you not to carry one.

If you find your reliever medicine is not working as well as before, or you need to take more than usual, go and see your doctor.

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

Contact your doctor if you experience blurred vision or other visual disturbances.

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before using Flixotide.

Other medicines and Flixotide

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go into hospital.

In particular tell your doctor or pharmacist if you are taking any of the following:

- a type of antiviral medicine known as a 'protease inhibitor' (such as ritonavir) or cobicistat containing products which may increase the effects of fluticasone propionate. Your doctor may wish to monitor you 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 doctor or pharmacist before using Flixotide.

Using Flixotide with food and drink

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

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 doctor for advice before taking this medicine.

Driving and using machines

Flixotide is not likely to affect you being able to drive or use any tools or machines.

3 How to use Flixotide

Flixotide Nebules come in two different strengths. Your doctor will have decided which strength you need. Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Using this medicine

- **Do not inject or swallow the liquid.** Flixotide Nebules should only be inhaled using your jet nebuliser. Using Flixotide Nebules with ultrasonic nebulisers is not generally recommended.
- The jet nebuliser produces a fine mist which you breathe in 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 some liquid.
- The liquid is put into a nebuliser. This makes a fine mist for you to breathe in through a face mask or mouthpiece. Use of a mouthpiece prevents the medicine 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 (or your child's) face with a barrier cream or wash your (or your child's) face thoroughly after treatment.
- Use your nebuliser in a well-ventilated room as some of the mist will be released into the air and may be breathed in by others.
- **It takes a few days for this medicine to work and it is very important that you use it regularly.**

Adults and Children over 16 years of age

- The usual starting dose is 0.5 to 2.0 mg (500 to 2000 micrograms) twice a day.
- Flixotide Nebules 0.5 mg/2 ml provides you with a dose of 500 micrograms.
- Flixotide Nebules 2.0 mg/2 ml provides you with a dose of 2000 micrograms.

Children (4 to 16 years of age)

- The usual starting dose is 1 mg (1000 micrograms) twice a day.

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

If you are using high doses of an inhaled steroid 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 doctor may decide to give you extra steroid medicines during this time.

Patients who have been on high doses of steroids, including Flixotide Nebules for a long time, must not stop taking their medicine suddenly without talking to their doctor. 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 your Nebules

1. the Nebules are in a foil pack. Do not open the pack until you need to use them
2. hold the top of the Nebule you have just removed. Twist the body to open it



3. put the open end of the Nebule into the nebuliser bowl and squeeze slowly to empty the content



4. assemble the nebuliser and use it as directed
5. repeat steps 2 to 4 to make up the dose needed if necessary

Diluting your Nebules

Do not dilute the contents of a Nebule unless you are told to by your doctor

- if your doctor has told you to dilute the solution, empty the contents of the Nebule into the nebuliser bowl
- add the amount of sterile sodium chloride 0.9% solution your doctor has told you to use
- put the top on the nebuliser bowl and shake gently 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. Only open a new one 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 bowl
- clean your nebuliser in the recommended way

If you use more Flixotide than you should

If you use more than you were told, **talk to your doctor as soon as possible.**

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 forget to use Flixotide

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

If you stop using Flixotide

- **Do not stop treatment** even if you feel better unless told to do so by your doctor. If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop using this medicine and talk to your doctor 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 weals 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 and light headed and collapse
- your breathing or wheezing gets worse straight after using your inhaler.

Other side effects include:

Very common (may affect more than 1 in 10 people)

- thrush in the mouth and throat

Common (may affect up to 1 in 10 people)

- sore tongue or throat
- hoarseness of voice

Problems with your mouth and throat can be reduced by doing certain things straight after inhaling your dose. These are brushing your teeth, rinsing your mouth or gargling with water and spitting it out. Tell your doctor 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 and bronchitis (lung infection). Tell your doctor if you notice any of the following symptoms: increased sputum production, change in sputum colour, fever, chills, increased cough, increased breathing problems.
- Bruising.

Rare (may affect up to 1 in 1,000 people)

- thrush (candidiasis) in the oesophagus

Very rare (may affect up to 1 in 10,000 people)

- 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. This is more likely to happen if you use high doses for a long period of time. This can cause:
 - children and young people to grow more slowly
 - something called 'Cushing's syndrome'. This happens when you have too much steroid 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 doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

Although the 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
- nosebleeds
- blurred vision

Talk to your doctor as soon as possible if:

- after 7 days of using Flixotide your shortness of breath or wheezing does not get better, or gets worse
- you or your child is on high doses of inhaled steroid and become unwell with vague 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 is not stopped suddenly as this could make your asthma worse and could also cause problems with the body's hormones

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Flixotide

- Store Flixotide Nebules in the foil wrap, inside the carton.
- Do not store above 30°C. Keep the container in the outer carton in order to protect from light. Do not freeze. Store upright.
- If the foil wrap has not been opened, do not use this medicine after the expiry date which is stated on the pack after 'EXP'. The date refers to the last day of that month.
- Nebules removed from the foil wrap should be protected from light and used within 28 days.
- Opened Nebules should be stored in a fridge and used within 12 hours of opening
- Keep this medicine out of the sight and reach of children.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 Contents of the pack and other information

What Flixotide contains

- The active substance is fluticasone propionate
- The other ingredients are polysorbate 20, sorbitan laurate, monosodium phosphate dihydrate, dibasic sodium phosphate anhydrous, sodium chloride (salt), water.

What Flixotide looks like and contents of the pack

Flixotide Nebules are provided as a strip of 5 nebulas in a foil wrap. Each box contains 10 Flixotide Nebules

Marketing Authorisation Holder:

Glaxo Wellcome UK Limited
980 Great West Road
Brentford
Middlesex
TW8 9GS

Manufacturer:

Glaxo Operations UK Limited
(trading as Glaxo Wellcome Operations)
Harmire Road
Barnard Castle
Durham
DL12 8DT
United Kingdom

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name **Flixotide Nebules 0.5 mg/2 ml.**

PL 10949/0297

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