

- 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafty@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flixotide

- Store the nebulers inside the carton to protect the nebulers from light
- If the foil blister has not been opened, do not use Flixotide Nebules after the expiry date which is stated on the pack after 'EXP'. The date refers to the last day of that month
- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C.
- Do not freeze.
- Once Nebules have been removed from their packaging, protect from light and use within 28 days.
- Opened nebulers should be used immediately.
- Do not use this medicine if you notice discolouration.
- Store upright.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Flixotide contains

The active substance is fluticasone propionate. Each 2 mg/2 ml nebule contains 2 mg Fluticasone propionate in a 2ml suspension. Each ml of suspension contains 1 mg Fluticasone propionate. The other ingredients are polysorbate 20, sorbitan monolaurate, monosodium phosphate dihydrate, dibasic sodium phosphate, sodium chloride, water for injection.

What Flixotide looks like and contents of the pack

Flixotide is a white, opaque suspension. Each cardboard carton contains two foil flow wrap packs. Each pack contains a strip of five Nebules.

The Parallel Product Authorisation Holder is:

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Repackaged by:

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Is this leaflet hard to see or read?
Phone LTT Pharma Limited,
Tel: +44 (0)1527 505414 for help.**

Package Leaflet: Information for the user

Flixotide® Nebules® 2 mg/2 ml Nebuliser Suspension

(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. 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 leaflet. See section 4.

Your medicine is called Flixotide Nebules 2mg/2ml Nebuliser Suspension and will be referred to as Flixotide throughout the rest of this leaflet.

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 contains a medicine called fluticasone propionate which belongs to a group of medicines called corticosteroids (a group of synthetic hormones, often just called steroids). Flixotide works by reducing swelling and irritation in the lungs. It has an anti-inflammatory action. Only a very small dose is needed as it is inhaled straight to the lungs.

Flixotide helps to prevent and treat asthma attacks in adults and children over 16 years of age who need regular treatment. This is why it is sometimes called a 'preventer'. It needs to be used regularly, every day. Flixotide also helps treat asthma attacks in children 4 years of age and over.

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 Flixotide:

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

Warnings and Precautions

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

- you have ever been treated for tuberculosis (TB)
- you have ever had thrush in your mouth.
- 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.
- you have been diagnosed with diabetes mellitus (Flixotide may increase your blood sugar)
- Contact your doctor if you experience blurred vision or other visual disturbances, which may be caused by cataract or glaucoma.

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

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

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 effect 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.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

3. How to use Flixotide

Flixotide Nebules come in two different strengths. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You should not increase or decrease your dose without seeking medical advice.

Using this medicine

- **Shake before use.**
- **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 convulsions.

Using your Nebules

1. The Nebules are in a foil flow wrap pack. Each pack contains a strip of 5 Nebules. Do not open the pack until you need to use them. Once Nebules have been removed from their packaging, protect from light and use within 28 days.
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 injection BP 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 injection BP should be used.

After use

- use a fresh Nebule for each dose. Only open a new one when you are ready to use it. Once opened, use immediately. If there is any liquid left over, throw it away.
- 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.**

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 product, 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 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 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)

- hoarseness of voice
- Bruising

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.

Rare (may affect up to 1 in 1000 people)

- thrush (candidiasis) in the oesophagus

Very rare (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 be affected when using Flixotide (adrenal suppression). 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.

Frequency not known, but may also occur

- Depression or aggression. These effects are more likely to occur in children.
- nosebleeds
- Blurred vision (that may be due to cataract or glaucoma).

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.