

FLIXOTIDE® NEBULES®

Fluticasone propionate

Consumer Medicine Information

Please read this leaflet carefully before you start Flixotide Nebules

What is in this leaflet

This leaflet answers some common questions about Flixotide Nebules. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Flixotide Nebules against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Flixotide Nebules are used for

Flixotide Nebules contains a medicine called fluticasone propionate. This medicine belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. They are not 'anabolic steroids' which are the steroids sometimes misused by athletes. Corticosteroids are used to treat asthma because they reduce the swelling and irritation in the walls of the small air passages in the lungs and so ease breathing problems.

Your doctor has chosen this medicine to suit you and your condition. Flixotide Nebules are used with a nebuliser (or 'pump') to help when your asthma is worse than normal, or to help your doctor to reduce or gradually stop the oral steroids you are taking. Flixotide Nebules are not

used ALONE to control sudden attacks of breathlessness.

This medicine is only one part of a general plan to help you manage your asthma. You should discuss this plan with your doctor. You will probably also be using a 'reliever puffer'. Keep using it according to your doctor's advice. Ask your doctor to check your treatment regularly.

The medicine in Flixotide Nebules is not addictive.

Flixotide Nebules generally does not cause any problems with your ability to drive a car or operate machinery.

Before you use Flixotide Nebules

When you must not use it

- **Do not use Flixotide Nebules if you have ever had an allergic reaction to Flixotide, fluticasone propionate or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, tongue or throat, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

- **Do not use Flixotide Nebules if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor will discuss the risks and benefits of using Flixotide Nebules if you are pregnant or breastfeeding.

- **Do not use Flixotide Nebules after the expiry date (Exp) printed on the pack.** If you use it after the expiry date has passed, it may not work as well.
- **Do not use Flixotide Nebules if the packaging is torn or shows signs of tampering.**
- **Ask your doctor if you have any questions about why Flixotide Nebules has been prescribed for you.**

Before you start to use it

You must tell your doctor if:

- you are taking other steroid medicines by mouth or inhalation. If you are already taking steroid tablets, you should carry a warning card about needing extra oral steroids during periods of stress eg. worsening asthma attacks, chest infections, surgery, trauma and other major illnesses occurring at the same time. Discuss this with your doctor.
- you have ever had to stop taking other asthma medicines.
- you have tuberculosis (TB) of the lung or other long term lung infection.
- you are allergic to foods, dyes, preservatives or any other medicines.
- you have had thrush in your mouth.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a

prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. For example, medicines like ketoconazole, used to treat fungal infection, and ritonavir used to treat HIV infection, may affect how Flixotide Nebules works. If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

How to use Flixotide Nebules

How to use it

The medicine in Flixotide Nebules is to be breathed into the lungs.

Flixotide Nebules should only be used with a jet nebuliser, not an ultrasonic nebuliser. The liquid in the Nebule is changed into a fine mist of droplets by the nebuliser. You should breathe the mist into your lungs, through your mouth. This is done through a mouthpiece, or a face mask, connected to the nebuliser. Some of the medicine is likely to be breathed in through your nose if you use a face mask. When you use a face mask, protect the skin exposed to the mist with barrier cream, and wash your face thoroughly after use.

Do not swallow the contents of your Flixotide Nebules.

This medication will be given to you under the direction of a doctor. If you are not sure about anything ask your doctor. The starting dose depends on how bad your asthma is, but it may then be changed as your condition improves.

Instructions for use and handling

Refer to the manufacturer's instructions on how to use the nebuliser properly. If you have any difficulties or do not understand the instructions for the nebuliser, ask your doctor or pharmacist.

It is important that the contents of your Nebule are well mixed before use. While holding the Nebule horizontally by the labelled tab, 'flick' the other end a few times and shake. Repeat this process several (at least three) times until the entire contents of the Nebule are completely mixed.

To open your Nebule, twist the tab at the top.

It is advisable to inhale your medicine using a mouthpiece. If you are using a face mask, protect your exposed facial skin with barrier cream, and wash your face well after using the medicine.

If you need to dilute your medicine, always use Sodium Chloride Injection BP.

Throw away any medicine which remains in the nebuliser bowl after use.

Use your nebuliser in a well ventilated room.

It is wise to visit your doctor or pharmacist from time to time to check that you are using your nebuliser in the right way. You should also contact the manufacturer of your nebuliser if you think that your nebuliser is not working properly. If you are not breathing the medicine in correctly, the medicine may not be helping you as much as it could.

How much to use

The usual doses are:

Adults and children over 16 years:
The dose is usually 2 mg twice daily.

Children and adolescents from 4 to 16 years:
The dose is usually 1 mg twice daily.

Your doctor will decide what dose you should use, how often you should use it, and what strength of Flixotide Nebules you should use.

When not to use it

Do not use ONLY Flixotide Nebules to treat a sudden attack of breathlessness. You will need a

different kind of medicine called a 'reliever' which your doctor will have told you to use. Tell your doctor if you need more of your 'reliever' than you usually do.

How long to use it

It takes a few days for this medication to work and it is very important that you use it regularly as told by your doctor. Do not stop treatment even if you feel better unless told to do so by your doctor. Also, do not increase your medicine unless told to do so by your doctor.

If you forget to use it

If you forget to take a dose, do not worry. Just take the next dose when it is due.

Do not take a double dose to make up for the dose that you missed.

If your breathing or wheezing gets worse straight after taking your medicine, stop using it immediately and tell your doctor as soon as possible.

If your shortness of breath and wheeze actually gets worse over several days, despite taking your new medicine, or if you find you are increasing the use of your reliever puffer, tell your doctor immediately.

If you have used too much (overdose)

If you have used more Flixotide Nebules than directed, you should ask your doctor if your medicine dose needs to be adjusted.

While you are using Flixotide Nebules

Things you must do

Tell your doctor or pharmacist that you are using Flixotide Nebules if you are about to be started on any new medicines.

If you have to go into hospital for an operation, take your Flixotide Nebules with you and tell the

doctor what medicine(s) you are taking.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.

Otherwise, your doctor may think that your medicine was not effective and change your treatment unnecessarily.

Things you must not do

Do not stop using Flixotide Nebules, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Flixotide Nebules to treat any other complaints unless your doctor says to.

If your Flixotide Nebules does not have the usual effect

If your chest condition gets worse, tell your doctor.

IMPORTANT: IF YOUR BREATHING SUDDENLY BECOMES MORE DIFFICULT JUST AFTER YOU HAVE USED YOUR FLIXOTIDE NEBULES, YOU WILL NEED TO USE A 'RELIEVER PUFFER' AND TELL YOUR DOCTOR IMMEDIATELY.

Tell your doctor as soon as possible if:

- your 'reliever puffer' does not help your breathing as much as usual
- the effect of your 'reliever puffer' does not last as long as usual
- you need more puffs of your 'reliever puffer' than usual to get relief.

Side-Effects

Check with your doctor as soon as possible if you have any problems while using Flixotide Nebules, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Flixotide Nebules can cause some side-effects. Do not be alarmed by this list of possible side-effects. You may not experience any of them. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- a sore throat or tongue. This may be due to 'thrush' (candida infection)
- hoarseness or throat irritation

Tell your doctor or pharmacist immediately if you notice any of these signs, but do not stop treatment unless told to do so.

For these, it may be helpful to rinse your mouth with water and spit it out after using your Flixotide Nebules. Your doctor may prescribe treatment for the 'thrush' in your mouth while you continue to use your Flixotide Nebules.

It is possible that some people, particularly those taking higher doses of Flixotide Nebules for a long time, may rarely suffer from the following side effects:

- rounded face
- loss of bone density
- eye problems (eg. cataract, glaucoma)
- slowing of growth in children. It is unclear what, if any, difference this makes to their final height.
- soreness in the food pipe (oesophagus)

Taking high doses of steroids for a long time could affect the adrenal glands, which make the body's own steroid. Your doctor may do tests to check how the adrenal glands are

working. Your doctor will be able to answer any questions you may have.

It is important that:

- prolonged treatment with Flixotide Nebules should not be stopped suddenly
- all doctors treating you are aware that you are on inhaled steroids. If your body is stressed by, for example, severe infection, surgical operation, an accident etc, you may need steroid tablets or injections for a time.

Very rarely the person taking the medicine may feel anxious, have disturbed sleep or notice increased irritability (mainly in children).

There may be an increase in the amount of sugar (glucose) in your blood. If you have diabetes, more frequent blood sugar monitoring and possibly adjustment of your usual diabetes treatment may be required.

If you feel unwell in any other way or have any symptoms that you do not understand, you should ask your doctor immediately.

Ask your doctor or pharmacist to answer any questions you may have.

If you think you are having an allergic reaction to Flixotide Nebules, tell your doctor immediately or go to the casualty department at your nearest hospital. Symptoms usually include some or all of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

After using Flixotide Nebules

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep Flixotide Nebules away from frost, direct heat or light. Do not freeze it. Store your Flixotide Nebules upright, at below 30°C.

Do not leave it in the car or on window sills. Heat can destroy some medicines.

Do not use after the date shown as 'Exp' on the carton and label.

Unused Nebules should be discarded 1 month after opening of the foil. Individual opened Nebules should be kept in a refrigerator, and thrown out if not used within 12 hours after opening.

Disposal

If your doctor tells you to stop using Flixotide Nebules, or the product has passed its expiry date, ask your pharmacist what to do with any Flixotide Nebules left over.

Product description

What Flixotide Nebules look like

Flixotide Nebules are provided as strips of 5 nebulas in a foil flow wrap. Each carton contains 10 nebulas.

Ingredients

Flixotide Nebules contain the medicine called fluticasone propionate (micronised) in a 2 millilitre (mL) suspension. It also contains polysorbate 20, sorbitan monolaurate, sodium phosphate - dibasic anhydrous, sodium phosphate - monobasic, sodium chloride and water as non-active ingredients.

Flixotide Nebules are available in two strengths:

- 0.5 milligram of fluticasone propionate in a 2 mL ampoule
- 2 milligrams of fluticasone propionate in a 2 mL ampoule

Other types of asthma medicines

Your Flixotide Nebules contains the kind of asthma medicine known as a 'preventer'. There are other types of inhalers that relieve your breathing problems when you are wheezing or your chest is tight. These medicines are called 'relievers'. Your doctor may tell you to use a 'reliever' in addition to your Flixotide Nebules.

Sponsor

GlaxoSmithKline Australia Pty Ltd
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Abbotsford, Victoria 3067

Further Information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 3 February 2017.

The information provided applies only to: Flixotide® Nebules®.

Flixotide, Nebule and Nebules are registered trade marks of the GSK group of companies.

Flixotide (fluticasone propionate) Nebules:

2 milligrams of fluticasone propionate in a 2 millilitre ampoule, AUST R 69002

0.5 milligram of fluticasone propionate in a 2 millilitre ampoule, AUST R 69004

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