



ALLEN & HANBURY'S

Flixonase™ Nasule™ Drops

fluticasone propionate

Patient Information Leaflet for Flixonase Nasule Drops

Your doctor has decided to prescribe Flixonase Nasule Drops. This leaflet tells you about your nasal drops and how to use them. Please read it carefully before using your Nasule Drops and keep it until you have finished the medicine.

WHAT ARE FLIXONASE NASULE DROPS?

Flixonase Nasule Drops contain 400 micrograms (1mg/ml) of the active ingredient, fluticasone propionate, as an aqueous suspension in each Nasule. They also contain polysorbate 20, sorbitan laurate, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, sodium chloride and water for injections.

Each carton contains 4 strips of 7 Nasules™ (28 Nasules in total).

WHO MAKES YOUR MEDICINE?

Flixonase Nasule Drops are manufactured by Glaxo Operations UK Ltd., Barnard Castle, County Durham, DL12 8DT. The product licence is held by Allen & Hanburys, Stockley Park, Middlesex, UB11 1BT.

HOW YOUR MEDICINE WORKS

Fluticasone propionate is one of a group of medicines called corticosteroids which are often referred to simply as 'steroids'. Fluticasone propionate has an anti-inflammatory action, and when used in the nose helps to reduce swelling and irritation.

Fluticasone propionate should not be confused with anabolic steroids misused by some athletes and taken as tablets or injection.

USES

Flixonase Nasule Drops are used for the regular treatment of nasal polyps and associated symptoms of nasal obstruction.

MAKE SURE THAT THIS MEDICINE IS SUITABLE FOR YOU

TELL YOUR DOCTOR BEFORE STARTING TO TAKE THIS MEDICINE

- * if you have ever had to stop taking this or another medicine for this illness because you were allergic to it or it caused problems,
- * if you are pregnant (or intending to become pregnant),
- * if you are breast-feeding a baby,
- * if you have ever had an operation on your nose,
- * if you have an infection in your nose,
- * if you have recently been treated with injected steroids or if you have been taking oral steroids for a long time.

Sometimes this medicine may not be suitable and your doctor may want to give you something different.

In some cases, Flixonase Nasule Drops may not be suitable to use with other medicines so be sure you tell your doctor:

- * if you are taking a type of antiviral medicine known as a protease inhibitor (e.g. ritonavir)
- * if you are taking certain medicines used to treat fungal infections (e.g. ketoconazole) or an antibiotic (e.g. erythromycin).

Check with your pharmacist or doctor if you are not sure.

Make sure that your doctor knows what other medicines you are taking, including any you have bought from the chemist. Remember to take these medicines with you if you have to go into hospital.

USING YOUR NASAL DROPS

- * Follow the instructions shown later in the leaflet. If you have any problems, tell your doctor or pharmacist.
- * Make sure you know HOW, WHEN and HOW MANY Nasules you should use. Your doctor should have told you and the instructions should be on the pharmacist's label. If they are not, or you are not sure, ask your doctor or pharmacist.
- * ONLY USE IN YOUR NOSE.
- * Avoid contact with your eyes and broken skin.

DOSE

For adults 18 years of age and over:

Use the contents of one Nasule (400 micrograms) in the nose once or twice a day. The dose should be divided between the affected nostrils. Your doctor will prescribe the lowest dose of Flixonase Nasule Drops that will best control your symptoms.

Flixonase Nasule Drops are not recommended for children or adolescents under 18 years of age.

- * DO NOT use a larger dose or use more Nasules than your doctor told you to.
- * It may take a few weeks for this medicine to work and it is VERY IMPORTANT THAT YOU USE IT REGULARLY. DO NOT STOP TREATMENT even if you feel better unless told to do so by your doctor. If your symptoms do not improve after four to six weeks, your doctor may decide to change your medicine.

IF YOU TAKE TOO MUCH

- * Tell your doctor if you accidentally use more than you were told to.

IF YOU MISS A DOSE

- * If you miss a dose, just use the next dose when it is due.

AFTER USING YOUR NASAL DROPS

- * In the unlikely event of you using high doses of Flixonase Nasule Drops over a long period of time, you may require extra steroids in times of extreme stress, or during admission to hospital after a serious accident or injury, or before a surgical operation. Your doctor may decide to give you extra steroid medication during this period as tablets, or by injection if you are in hospital.

SIDE EFFECTS

Most people do not have any problems after using Flixonase Nasule Drops.

- * Sometimes the nasal drops may cause dryness or irritation of your nose or throat.
- * Occasionally people have a nose bleed after using the nasal drops, but this soon stops. If you have a bad nose bleed, tell your doctor as soon as possible.
- * There have been very rare reports of a severe allergic reaction to this medicine. If you suddenly develop a rash, swelling (usually of the face, lips or tongue) or difficulty with your breathing, stop using your Flixonase Nasule Drops and contact your doctor IMMEDIATELY.
- * In very rare instances, treatment with Flixonase Nasule Drops may affect the normal production of steroids in the body. This is more likely to happen if high doses are being used over a long period of time. Your doctor will help prevent this happening by prescribing the lowest dose of steroid at which your symptoms are well-controlled.
- * Very rarely people have problems with their eyes after using the nasal drops. If you experience pain or blurred vision, tell your doctor as soon as possible.
- * Nasal damage (nasal septal perforation) has been reported in extremely rare instances.

If you feel unwell or have any other problems, tell your doctor or pharmacist and follow their advice.

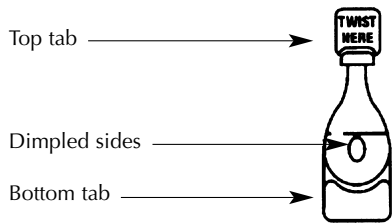
STORING YOUR MEDICINE

Keep your nasal drops in a safe place WHERE CHILDREN CANNOT REACH THEM.

Keep Flixonase Nasule Drops in their foil wrapper, in the carton and stored in an upright position. Do not freeze. Do not store above 30°C (86°F). Discard any unused Nasules 28 days after first opening their foil wrapper. Do not use the nasal drops after the date shown as 'EXP' on the Nasule, foil wrapper or carton.

If you are told to stop taking this medicine, return any Flixonase Nasule Drops to your pharmacist to be destroyed.

What the Nasule looks like

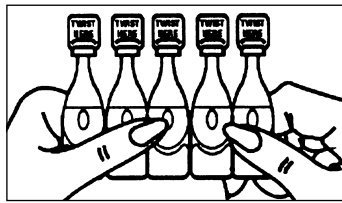


How to use the Nasules

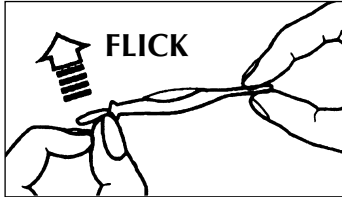
1 Gently blow your nose to clear.

2 Open the foil wrapper by tearing off one side. Do not open the foil wrapper until the Nasules are required.

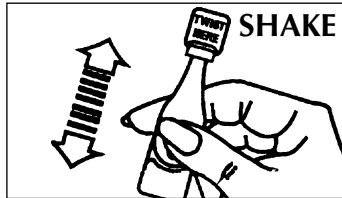
3 Detach one Nasule from the strip and return the remaining Nasules to the foil wrapper. Put the foil wrapper back in the carton.



4 It is important to ensure that the contents of your Nasule are well mixed before use.

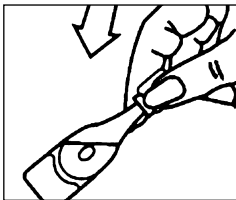


While holding the Nasule horizontally by the larger tab, 'flick' the other end a few times and shake.

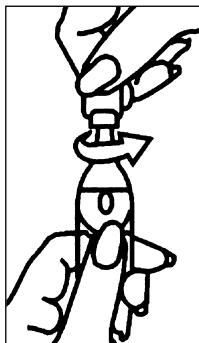


Repeat this process several times until the entire contents of the Nasule are completely mixed.

5 Hold the top tab of the Nasule and flick or shake downwards with a quick motion. This will remove any liquid from the neck of the Nasule.

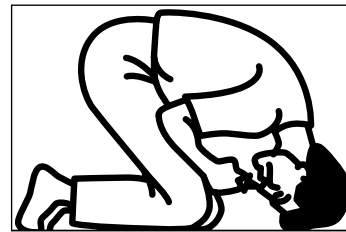


6 Hold the bottom tab of the Nasule securely. Twist and remove the top tab.



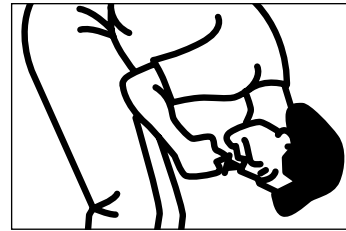
7 Your doctor should have told you how to put the nasal drops in your nose. To make sure that your medicine reaches the affected area, you will need to get into one of the positions shown:

POSITION A - Kneel on the floor, bend forward and rest the top of your head on the floor.



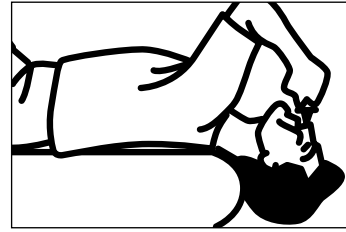
or

POSITION B - Sit or stand, bend forward until your head is at knee level.



or if you find these positions difficult:

POSITION C - Lie on your back on a bed with your head tilted backwards over the edge.



Put the Nasule into the nostril and gently squeeze to deliver 6 drops. This is approximately half the dose. **Be careful not to get the nasal drops in your eyes.** If you do, rinse with water straightaway.

Important:

If you cannot easily count the drops, make sure you hold the Nasule by the dimpled sides. When the Nasule is in the nostril, squeeze until the dimpled sides meet. This will deliver about half the dose.

Transfer the Nasule to your other nostril and squeeze it to deliver the remaining drops.

If you are in Position A or B, keep your head in this position for at least 1 minute.

If you are in Position C (lying down), rest your head sideways on the bed as soon as possible.

Remember:

One Nasule holds enough drops for use in both nostrils.

Use all the Nasules from one foil wrapper before opening a new wrapper.

Discard the Nasules after use.

FURTHER INFORMATION

REMEMBER: This medicine is for YOU. Only a doctor can prescribe it for you. Never give it to someone else. It may harm them even if their symptoms are similar.

This leaflet does not tell you everything about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

You will be able to find out more information about prescribed medicines from books in public libraries.

The information in this leaflet only applies to Flixonase Nasule Drops. Flixonase, Nasules and Nasule are trademarks of the GlaxoSmithKline group of companies.

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