

## Package Leaflet: Information For The User

### **Flixonase™ Nasule™ Drops 400 micrograms (1 mg/ml), nasal drops suspension.**

fluticasone propionate

#### **Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Flixonase Nasule Drops are and what they are used for
2. Before you use Flixonase Nasule Drops
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#### **1. What Flixonase Nasule Drops are and what they are used for**

Flixonase Nasule Drops contain a medicine called fluticasone propionate. This belongs to a group of medicines called steroids (also called ‘corticosteroids’).

- Steroids work by reducing inflammation
- they reduce swelling and irritation in your nose
- this helps to relieve itching, sneezing and your blocked or runny nose.

Flixonase Nasule Drops are used to treat:

- Small growths inside the nose (polyps)
- Symptoms associated with nasal obstruction.

Flixonase Nasule Drops are provided in small plastic containers (Nasules).

#### **2. Before you use Flixonase Nasule Drops**

##### **Do not use Flixonase Nasule Drops if:**

- you are allergic (hypersensitive) to fluticasone propionate or any of the other ingredients of Flixonase Nasule Drops (listed in section 6).

##### **Take special care with Flixonase Nasule Drops**

Check with your doctor or pharmacist before using your medicine if:

- you have an infection in your nose.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Flixonase Nasule Drops

Flixonase Nasule Drops may lower the normal production of steroid hormones in your body, particularly if doses higher than those recommended are used for a long time. In this situation people may need to take extra steroids in times of extreme stress, following serious injury or before a surgical operation.

It is important therefore that you are taking the lowest dose of Flixonase Nasule Drops to control your symptoms. Your doctor will check you for signs of any problems.

### **Taking other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes herbal medicines.

Check with your doctor or pharmacist before using your medicine if:

- you are taking a type of antiviral medicine known as a protease inhibitor (such as ritonavir)
- you are taking a medicine used to treat fungal infections (such as ketoconazole)
- you have had steroids for a long time, either as an injection or by your mouth.

### **Pregnancy and breast-feeding**

Do not use Flixonase Nasule Drops if you are pregnant, or planning to become pregnant, or if you are breast-feeding, unless your doctor or pharmacist tells you to.

### **Driving and using machines**

Flixonase Nasule Drops are not likely to affect you being able to drive or use any tools or machines.

## **3. How to use Flixonase Nasule Drops**

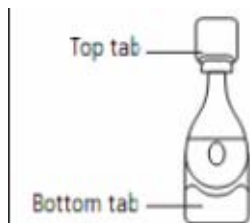
Always use Flixonase Nasule Drops exactly as your doctor has told you to. Don't exceed the recommended dose. Check with your doctor or pharmacist if you're not sure.

- Do not use in children or young people under 16 years old.
- Only use in your nose, contact with the eyes should be avoided.
- It may take a few weeks for this medicine to work. So keep using it, even though you may not feel better straight away.
- You should use Flixonase Nasule Drops every day.

### **How much to use - adults (over 16 years of age)**

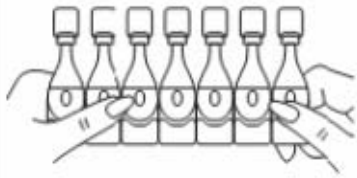
- The usual starting dose is one single-use plastic container (400 micrograms) divided equally between each nostril, once or twice a day.
- As your symptoms improve, your doctor may ask you to use a lower dose.
- If your symptoms do not improve after 4 to 6 weeks your doctor may change your medicine.

### **What the plastic container looks like**



### **Using your Flixonase Nasule drops**

1. Open the foil pack by tearing off one side. Do not open the pack until the drops are needed.
2. Take out the strip of plastic containers from the foil and pull off one container.



3. Put the remaining containers back into the foil pack and put the pack back in the box.
4. Flick and shake the plastic container several times. The contents of the container **must be well mixed** before use.
5. Then shake downwards to make sure the liquid is not in the neck of the container.
6. Hold the bottom tab of the container firmly. Twist and remove the top tab to open it.



### How to put the drops in

Before you put the drops in, you must choose one of the positions shown in these pictures. Although they may not be easy, the positions will make sure the drops get to where they are needed.

1. Gently blow your nose to clear it.
2. While standing up, bend right over.



3. If you can't do this, kneel down and then bend right over.



4. Put the opened container into one nostril and gently squeeze.
5. Keep squeezing until the sides of the container touch each other. This will mean that about half the dose has been given (about 6 drops).
6. Repeat this step to use the rest in your other nostril.
7. Stay with your head down for at least one minute after putting the drops in.

If these positions are difficult you can lie on a bed with your head tilted over the edge. After you have put the drops in, rest your head sideways on the bed for at least one minute.



**Be careful not to get the drops in your eyes or on broken skin.** If you do, rinse your eyes or skin with water immediately.

### If you forget to use Flixonase Nasule Drops

If you miss a dose, just use the next dose when it is due. Do not use a double dose to make up for a forgotten dose.

**If you use more Flixonase Nasule Drops than you should**

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

**If you stop taking Flixonase Nasule Drops**

Do not stop treatment even if you feel better, unless your doctor tells you to stop. If you do stop, the symptoms may come back.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Flixonase Nasule Drops can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

**Allergic reactions: get a doctor's help straight away**

A small number of people get allergic reactions to Flixonase Nasule Drops, which can develop into a more serious, even life-threatening problem if not treated. Symptoms include;

- becoming very wheezy, coughing or having difficulty with breathing
- suddenly feeling weak or light-headed (which may lead to collapse or loss of consciousness)
- swelling around the face, mouth or tongue
- skin rashes or redness.

In many cases, these symptoms will be signs of less serious side effects. But you must be aware that they are potentially serious — so, if you notice any of these symptoms:

**See a doctor as soon as possible.**

Allergic reactions to Flixonase Nasule Drops are very rare (These affect less than 1 in 10,000 people).

Other side effects include:

**Very common** (affects more than 1 in 10 people)

- Nose bleeds.

**Common** (affects less than 1 in 10 people)

- A dry or irritated nose or throat.

**Very rare** (affects less than 1 in 10,000 people)

- Cloudy lens (cataract), increased pressure in the eye that can cause problems with vision (glaucoma). These eye problems occurred in people who used Flixonase Nasule Drops for a long time.
- Small holes (perforations) in the ridge inside the nose that separates the nostrils.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

In addition, the production of steroids in your body may be affected. This is more likely to happen if you use high doses for a long time. Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

**5. How to store Flixonase Nasule Drops**

- Keep out of the reach and sight of children.
- Do not store above 30°C.

- Do not freeze.
- Store Flixonase Nasule Drops in their foil wrapper and in the carton in an upright position.
- Do not use Flixonase Nasule Drops after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.
- Discard any unused Flixonase Nasule Drops 28 days after first opening the foil wrapper.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Further information**

### **What Flixonase Nasule Drops contain**

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

### **What Flixonase Nasule Drops looks like and contents of the pack**

Each container contains 400 micrograms of fluticasone propionate, giving a strength of 1 milligram per millilitre. Each carton contains 4 strips of 7 Nasules (28 Nasules per carton), or 12 strips of 7 Nasules (84 Nasules per carton). Not all pack sizes may be available.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Glaxo Wellcome UK Limited trading as Allen & Hanburys  
 Stockley Park West  
 Uxbridge  
 Middlesex  
 UB11 1BT

#### **Manufacturer**

Glaxo Operations UK Ltd  
 Barnard Castle  
 Durham  
 DL12 8DT

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

Denmark	Flixonase næsedråber
Finland	Flixonase nenätipat
Germany	Flutide Nasetten
Netherlands	Flixonase Nasules
Spain	Flixonase Gotas Nasaes
Sweden	Flutide Nasal nasdroppar
UK	Flixonase Nasule Drops

#### **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**     **Flixonase Nasule Drops**

Reference number 10949/0323

This is a service provided by the Royal National Institute of Blind People.

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