

## **Package leaflet: Information for the user**

### **Flixonase 50 micrograms/actuation nasal spray, suspension** fluticasone Propionate

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

- Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### **What is in this leaflet**

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

#### **1. What Flixonase is and what it is used for**

The active ingredient is fluticasone propionate, a corticosteroid which, when used every day, has an anti-inflammatory action. This spray helps to control your body's reactions to allergens ('triggers') in the environment.

Flixonase is used in adults aged 18 and over to treat the allergic symptoms of hayfever and other airborne allergies such as allergy to pets, dust mites and mould spores. It relieves symptoms including sneezing, itchy and watery eyes and a runny, itchy or blocked-up nose, for up to 24 hours.

It may take 3 or 4 days to build up to the maximum level of protection. Therefore it is important to continue regular use to achieve full therapeutic benefit.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### **2. What you need to know before you use Flixonase**

##### **Do not use Flixonase**

- 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 or pharmacist before using Flixonase:

- if you are using corticosteroid medicines (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops).
- if you have an infection in your nose or sinuses, or have a cold, if you have a high temperature, if you have recently had surgery, an injury or ulcers in your nose.

If your symptoms do not improve after 7 days, talk to your doctor.

Do not use continuously for more than 3 months unless your doctor tells you to.

Contact your doctor if you experience blurred vision or other visual disturbances, which could be caused by conditions such as cataract or glaucoma.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents and more rarely bone mineral density, effects on glucose metabolism and a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Treatment with higher than recommended doses of nasal corticosteroids may result in clinically significant adrenal suppression. If there is evidence for higher than recommended doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

### **Other medicines and Flixonase**

Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription ; particularly:

- corticosteroid medicines (including eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops)
- ritonavir or cobicistat ( anti-HIV medicines)
- ketoconazole (for fungal infections).

Some medicines may increase the effects of **Flixonase** and your doctor may wish to monitor you carefully if you are taking these medicines( including some medicines for HIV : ritonavir, cobicistat).

### **Flixonase with food and drink**

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

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. There are no data on the effects of this medicine on fertility.

### **Driving and using machines**

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

### **Flixonase contains benzalkonium chloride**

This medicine contains 0.02 mg benzalkonium chloride per dose in a nasal spray equivalent to 0.2 mg benzalkonium chloride in 1 ml nasal spray suspension.

Benzalkonium chloride may cause nasal irritation or swelling, especially with prolonged use.

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **Dose for adults aged 18 years and over:**

The recommended dose is two sprays into each nostril once a day (200 micrograms fluticasone propionate), ideally in the morning.

Once your symptoms have improved, you may be able to reduce the dose to one spray into each nostril once daily.

If your symptoms are especially bad, you may need to increase the dose to two sprays into each nostril twice daily until your symptoms improve but this is for short term use only.

- Do not spray more than 8 sprays (4 per nostril) in a day.
- Use the lowest dose possible to control your symptoms.
- If your symptoms do not improve, or are not well controlled, after 7 days, talk to your doctor or pharmacist.
- Do not use more than the recommended dose.

**Use in children and adolescents:**

Not to be used in children and adolescents under 18 years of age.

**Method of administration**

Only use in the nose.

Do not swallow.

Do not spray in your eyes.

**Before using a new bottle of Flixonase:**

Flixonase has a cap which protects the nozzle and keeps it clean. Take this cap off before you use the spray (Picture 1).

Before you start a new bottle of Flixonase, or if you have not used the spray for a few days, prime the device to ensure you get a correct dose.

Hold the bottle with your thumb underneath and your forefinger and middle finger either side of the nozzle. Keeping your thumb still, press down with your fingers several times until you get a fine mist (Picture 2).

When doing this, do not point the nozzle at yourself or someone else.

If the spray still doesn't work, clean it as described under the 'To clean the spray' section. Do not try to unblock or enlarge the tiny spray hole with a pin or other sharp objects because this will destroy the spray mechanism.

*Picture 1*

1



*Picture 2*

2



**Using Flixonase:**

- Blow your nose gently.
- Shake the bottle well and remove the cap.
- If it is a new bottle of Flixonase, or if you have not used the spray for a few days, you will need to prime the device. Press down on the pump several times until you get a fine mist.
- Hold the bottle as shown (Picture 3). Put the nozzle in one nostril and close the other nostril, tilt your head forward slightly and keep the bottle upright as shown (Picture 4). Aim slightly away from the centre of your nose.
- Start to breathe in slowly through your nose. While you are breathing in, press down firmly onto the collar with your fingers to squirt a mist into your nose.
- Breathe out through your mouth. Repeat step 4 to take a second spray in the same nostril.
- Remove the nozzle from this nostril and breathe out through your mouth (Picture 5).
- Repeat steps 4 to 6 for the other nostril.
- After using the spray, wipe the nozzle with a clean tissue or handkerchief and replace the cap.

*Picture 3*

3



*Picture 4*

4



*Picture 5*

5



**To clean the spray:**

- Take the cap and nozzle off (Picture 6).
- Soak the nozzle and cap in warm water for a few minutes (Picture 7) and then rinse under a running tap (Picture 8).
- Shake off the excess water and allow to dry in a warm place – not too hot!
- Re-fit the nozzle (Picture 9).
- If necessary, press the pump down several times until you get a fine mist. Replace the cap.
- Do not try to unblock or enlarge the tiny spray hole with a pin or other sharp objects because this will destroy the spray mechanism.

*Pictures 6, 7, 8, 9*

6



7



8



9



It may take 3 or 4 days to build up to the maximum level of protection provided by Flixonase. To prevent symptoms, start to use Flixonase before exposure to your usual ‘triggers’.

You should not use Flixonase for longer than the time you are exposed to your usual allergy ‘triggers’ (e.g. pollen).

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

Tell your doctor if you use more than is recommended.

**If you forget to use Flixonase**

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 missed dose.

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

#### **4. Possible side effects**

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

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

##### **Very rare but serious side effects, get medical help at once**

- Signs of an allergic reaction, such as a rash, swelling of the mouth or face, or having difficulty breathing.
- You get new changes to your vision that develop after starting this product. There have been rare reports of eye problems such as cataracts or glaucoma in people who have used large amounts of corticosteroids over a period of several years.
- You get small holes (perforations) in the ridge inside the nose that separates the nostrils. Eye problems such as pain

##### **Unknown frequency side effects**

It is not known how often these side effects occur but if they do, stop using the medicine and seek immediate medical help

- Blurred vision
- Sores in the nose

If you get any of these symptoms, stop using the medicine and seek immediate medical help.

##### **Other side effects**

##### **Very common side effects**

These may affect more than 1 in 10 people:

- Occasional nose bleeds

##### **Common side effects**

These may affect up to 1 in 10 people:

- Sneezing after using the spray but this soon stops.
- Unpleasant taste or smell.
- Dryness or irritation in the nose or throat.
- Headache.

##### **Very rare side effects**

These may affect up to 1 in 10,000 people:

- Nasal problems such as pain and/or persistent nose bleeds.

If you get any of these symptoms, stop using the medicine and tell your doctor.

##### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.ravimiamet.ee](http://www.ravimiamet.ee) By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Flixonase**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Flixonase contains**

- The active substance is fluticasone propionate. Each spray delivers 100 mg suspension containing 50 micrograms of fluticasone propionate as a delivered dose.
- The other ingredients are glucose (anhydrous), microcrystalline cellulose, carmellose sodium, phenylethyl alcohol, benzalkonium chloride, polysorbate 80 and purified water.

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

Flixonase is a white, opaque aqueous nasal spray, suspension.

The amber glass bottle is fitted with a pump, nasal applicator and cap. The bottle contains 60 sprays, with a total content not less than 7.0 g or 120 sprays with a total content not less than 14.0 g.

### **Marketing Authorisation Holder and Manufacturers**

#### Marketing Authorisation Holder

GlaxoSmithKline Dungarvan Limited  
Knockbrack  
Dungarvan  
Co Waterford  
Ireland

#### Manufacturers

Glaxo Wellcome SA  
09400 Aranda de Duero  
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