

Package Leaflet: Information For The User

Flixonase™ Aqueous Nasal Spray fluticasone propionate 50 micrograms

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 is and what it is used for
- 2 Before you use Flixonase
- 3 How to use Flixonase
- 4 Possible side effects
- 5 How to store Flixonase
- 6 Further information

1 What Flixonase is and what it is used for

Flixonase Aqueous Nasal Spray (called 'Flixonase' in this leaflet) contains a medicine called fluticasone propionate. This belongs to a group of medicines called steroids (also called 'cortico-steroids').

- 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 is used to prevent and treat:

- Inflammation in the lining of your nose (rhinitis) due to seasonal allergies, such as Hayfever.
- Inflammation in the lining of your nose (rhinitis) due to year round (perennial) allergies, such as animal allergies.

2 Before you take Flixonase

Do not use Flixonase if:

- You are allergic (hypersensitive) to fluticasone propionate or any of the other ingredients of Flixonase Aqueous Nasal Spray (listed in section 6: Further information).

Take special care with Flixonase

- If you have ever had an operation on your nose.
- If you have an infection in your nose

If you are unsure if the above apply to you, talk to your doctor or pharmacist before using Flixonase

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

Taking Flixonase with food and drink

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

Pregnancy and breast-feeding

Talk to your doctor before using this medicine if you are pregnant, might become pregnant, or are breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Flixonase

Flixonase contains benzalkonium chloride which may cause problems with your breathing (bronchospasm).

3 How to use Flixonase

Always use Flixonase exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- **Do not use in children under 4 years old.**
- **Only use in your nose, contact with eyes should be avoided.**
- **It takes a few days for this medicine to work. So keep using it, even though you may not feel better straight away.**
- Use the spray every day.

How much to use - adults and children (aged 12 and over)

- The usual starting dose is 2 sprays into each nostril once a day, preferably in the morning.
- The most you would use over 24 hours is normally 8 sprays (4 sprays per nostril).
- As you become better, your doctor may ask you to use a lower dose - one spray into each nostril once a day.
- If your symptoms then get worse, your dose may be increased back to the starting dose.

How much to use – children aged 4 to 11 years

- The usual starting dose is one spray into each nostril once a day, preferably in the morning
- The most you would use over 24 hours is normally 4 sprays (2 sprays per nostril)

If you use high doses of Flixonase

You may need extra steroids:

- in times of extreme stress
- during admission to hospital after a serious accident or injury
- before a surgical operation.

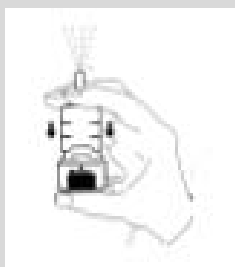
Your doctor may give you extra steroid medication such as tablets or an injection.

Preparing your spray

Each spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray.

A new spray (or one that has not been used for a few days), may not work first time. You need to 'prime' the spray by pumping the spray a few times until a fine mist is produced.

1. Hold the bottle as shown and make sure it is pointed away from you.
2. Put your forefinger and middle finger on the collar either side of the nozzle and put your thumb underneath the bottle.
3. Keep your thumb still, and press down with your fingers to pump the spray.



- If the spray does not work and you think it may be blocked, you will need to clean it. Please see the section below, **Cleaning your spray**.

- Never try to unblock or enlarge the tiny spray hole with a pin or other sharp object. This will damage the way the spray works.

Using your spray

- 1 Shake the bottle and take off the dust cap.
- 2 Blow your nose gently.
- 3 Close one nostril with your finger as shown, and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright. Hold the bottle as shown.



- 4 Start to breathe in slowly through your nose. While you are breathing in press down firmly on the collar with your fingers. A spray of fine mist will go into your nostril
- 5 Breathe out through your mouth.
- 6 Repeat step 4 to use a second spray in the same nostril.
- 7 Remove the nozzle from this nostril and breathe out through your mouth.
- 8 Repeat steps 3 to 6 for your other nostril.
- 9 After using your spray, wipe the nozzle carefully with a clean tissue or handkerchief, and replace the dust cap.

Cleaning your spray

Clean your spray at least once a week, or more often if it gets blocked.

- 1 Take the dust cap off by gently squeezing the ribbed sides between your finger and thumb and lifting it off. Do not twist it off.
- 2 Pull upwards on the white collar to remove the nozzle.



- 3 Soak the nozzle and dust cap in warm water for a few minutes.
- 4 Then rinse under a running tap.
- 5 Shake off the excess water and let them dry in a warm place.
- 6 Put the nozzle back on the spray.
- 7 'Prime' the bottle as described in the section above, **Preparing your spray**

If you forget to use Flixonase

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

If you use more Flixonase than you should

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

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should use only as much as your doctor recommends; using more or less may make your symptoms worse.

If you stop taking Flixonase

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 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, 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.

If this happens, tell your doctor straight away – you may need urgent medical treatment.

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

Immediately after you use your spray

- You may sneeze a little, but this soon stops.
- Very occasionally you may find you get an unpleasant taste or smell.

Tell your doctor as soon as possible if you notice any of the following side effects:

Other side effects include:

Very common (affects more than 1 in 10 people)

- Nose bleeds.

Common (affects less than 1 in 10 people)

- Headache.
- Unpleasant taste.
- Unpleasant smell.
- A dry or painful nose or throat.

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

- Skin reaction – which can range from red, itchy rash and blotches to a more severe skin reaction such as dry, cracked and peeling skin.
- Problems with your eyes such as pain or blurred vision.
- Damage to your nose

Very rarely, the normal 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. In children this side effect can rarely cause them to grow more slowly than others. Children who receive this treatment for a long period of time will have their height checked regularly by their doctor.

If you notice any side effects not listed in this leaflet tell your doctor as soon as possible.

5 How to store Flixonase

Keep out of the reach and sight of children.

- Protect from frost and light.
- Do not store above 30°C.
- Do not put in a refrigerator.
- Do not use Flixonase 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.
- If you are told to stop taking this medicine return any unused spray to your pharmacist to be destroyed.

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 Aqueous Nasal Spray contains

- The active substance is fluticasone propionate
- The other ingredients are microcrystalline cellulose, sodium carboxymethylcellulose, dextrose, polysorbate 80, purified water and the preservatives benzalkonium chloride and phenylethylalcohol. These other ingredients are needed to make a stable suspension which will not go off.

What Flixonase Aqueous Nasal Spray looks like and contents of the pack

Each amber coloured glass bottle delivers 150 sprays. Each spray contains 50 micrograms of fluticasone propionate.

Marketing Authorisation Holder

Glaxo Wellcome UK Ltd
Trading as Allen and Hanburys
Stockley Park West
Uxbridge
Middlesex
UB11 1BT.

Manufacturer

Glaxo Wellcome SA
Aranda de Duero
Burgos
Spain

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 Aqueous Nasal Spray

Reference number 10949/0036

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

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