

Package Leaflet: Information For The User

Flixonase[®] Aqueous Nasal Spray 50 micrograms (fluticasone propionate)

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

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

The name of your medicine is Flixonase Aqueous Nasal Spray 50 micrograms, but it will be referred to as Flixonase throughout this leaflet.

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

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

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Flixonase

Tell your doctor if you are taking, have recently taken or might take 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) or cobicistat containing products which may increase the effects of fluticasone propionate. Your doctor may wish to monitor you carefully if you are taking these medicines
- 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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

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

Flixonase contains 0.02mg benzalkonium chloride in each unit dose

Benzalkonium chloride may cause problems with your breathing (bronchospasm). Benzalkonium chloride may also cause irritation or swelling inside the nose, especially if used for a long time.

3 How to use Flixonase

Always use this medicine exactly as your doctor has told you. 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

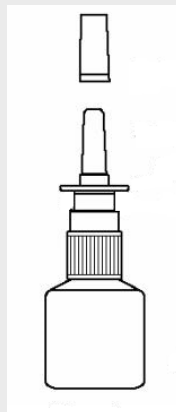
- 1 Shake the bottle and take off the dust cap.
- 2 Blow your nose gently.
- 3 Close one nostril with your finger as shown, and put the nozzle in the other nostril. Tilt your head forward slightly and keep the bottle upright. Hold the bottle as shown.
- 4 Start to breathe in slowly through your nose.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

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

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 medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine 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 (may affect more than 1 in 10 people)

- Nose bleeds.

Common (may affect up to 1 in 10 people)

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

Very rare (may affect up to 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

Not known: frequency cannot be estimated from the available data

- Blurred vision
- Sores in the 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Flixonase

- Keep out of the sight and reach of children.
- Do not store above 30°C.
- Do not use the spray after the expiry date which is stated on the carton and bottle labels after 'Exp'. The expiry date refers to the last day of that month.
- If the medicine becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
- Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.
- 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 Contents of the pack and other information

What Flixonase contains

The active substance is fluticasone propionate. Each metered spray contains 50 micrograms of fluticasone propionate.

The other ingredients are dextrose (anhydrous), microcrystalline cellulose, carmellose sodium, polysorbate 80, purified water and hydrochloric acid, dilute and the preservatives benzalkonium chloride and phenylethyl alcohol.

What Flixonase looks like and contents of the pack

Flixonase is a white, opaque suspension. It is available in a polypropylene bottle, with atomiser-dosing pump, nasal adapter and cap. Each bottle of Flixonase provides 120 sprays.

Manufactured by: Glaxo Wellcome SA, Avda Extremadura 3, E-09400 Aranda de Duero, Burgos, Spain.

OR

Glaxo Wellcome Operations UK, Ltd, Harmire Road, Barnard Castle County Durham DL12 8DT, UK.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Flixonase® Aqueous Nasal Spray 50 micrograms; PL 18799/1050

Leaflet date: 05.02.2021

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Flixonase is a registered trademark of the Glaxo Group Limited.

Blind or partially sighted?

Is this leaflet hard to see or read?

Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

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Fluticasone propionate Aqueous Nasal Spray 50 micrograms

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The name of your medicine is Fluticasone propionate Aqueous Nasal Spray 50 micrograms, but it will be referred to as Fluticasone propionate throughout this leaflet.

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- 2 What you need to know before you use Fluticasone propionate
- 3 How to use Fluticasone propionate
- 4 Possible side effects
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- 6 Contents of the pack and other information

1 What Fluticasone propionate is and what it is used for

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- Inflammation in the lining of your nose (rhinitis) due to seasonal allergies, such as Hayfever.
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2 What you need to know before you use Fluticasone propionate

Do not use Fluticasone propionate 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 Fluticasone propionate:

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Fluticasone propionate contains 0.02mg benzalkonium chloride in each unit dose

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- The usual starting dose is 2 sprays into each nostril once a day, preferably in the morning.
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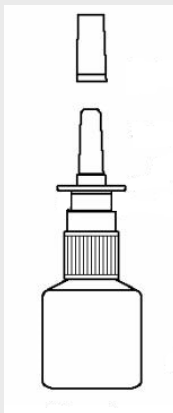
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- 9 After using your spray, wipe the nozzle carefully with a clean tissue or handkerchief, and replace the dust cap.



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**



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

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- 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 Fluticasone propionate 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 (may affect more than 1 in 10 people)

- Nose bleeds.

Common (may affect up to 1 in 10 people)

- Headache.
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- 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.
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Not known: frequency cannot be estimated from the available data

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By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Fluticasone propionate

- Keep out of the sight and reach of children.
- Do not store above 30°C.
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The other ingredients are dextrose (anhydrous), microcrystalline cellulose, carmellose sodium, polysorbate 80, purified water and hydrochloric acid, dilute and the preservatives benzalkonium chloride and phenylethyl alcohol.

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Fluticasone propionate is a white, opaque suspension.

It is available in a polypropylene bottle, with atomiser-dosing pump, nasal adapter and cap.

Each bottle of Fluticasone propionate provides 120 sprays.

Manufactured by: : Glaxo Wellcome SA,
Avda Extremadura 3, E-09400 Aranda de Duero, Burgos,
Spain.

OR

Glaxo Wellcome Operations UK, Ltd, Harmire Road,
Barnard Castle County Durham DL12 8DT, UK.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Fluticasone propionate Aqueous Nasal Spray
50 micrograms; PL 18799/1050

Leaflet date: 05.02.2021

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