

FLIXONASE AQUEOUS NASAL SPRAY

Fluticasone Propionate (0.05%w/w)

What is in this leaflet

1. What Flixonase is used for
2. How Flixonase works
3. Before you use Flixonase
4. How to use Flixonase
5. While you are using it
6. Side Effects
7. Storage and Disposal of Flixonase
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Flixonase is used for

Flixonase Aqueous Nasal Spray (called 'Flixonase' in this leaflet) is indicated for the prevention and treatment of seasonal allergic rhinitis including hay fever, and perennial rhinitis. In people with allergic rhinitis, Flixonase is also indicated for the management of associated sinus pain and pressure.

How Flixonase works

Flixonase 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.

Before you use Flixonase

- When you must not use Flixonase

Do not use if you are allergic to fluticasone propionate or to any other ingredient in the product.

- Before you start to use Flixonase

Take special care and check with your doctor before you use this medicine:

- if you have a high temperature or have been diagnosed with a sinus infection.
- if you have recently had surgery or an injury to the nose, or ulcers in the nose.
- if you have or have recently suffered from a nasal infection in or around the nose.
- if you are pregnant or planning to become pregnant (the use of Flixonase

should be avoided during pregnancy unless thought essential by the doctor).

- if you are breastfeeding.

- Taking other medicines

Check with your doctor or pharmacist before using this medicine:

- if you are taking ritonavir or cobicistat (a medicine used to treat HIV).
- if you are using ketoconazole (used to treat fungal infections).
- If you are using other corticosteroid medicines – these may include some eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops.

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.

How to use Flixonase

- How much to use

Adults and children 12 years and over: Use two sprays into each nostril once a day. Do not use more than four sprays into each nostril per day.

Children 4 to 11 years old: Use one spray into each nostril once a day. Do not use more than one spray into each nostril per day.

Do not use in children under 4 years old. Do not use more than the recommended dose.

- When to use it

Preferably in the morning.

- How long to use it

Adults and children 12 years old and older: The nasal spray should not be used for more than 6 months continuously without consulting a doctor.

Children 4 to 11 years old: The nasal spray should not be used for more than 2 months continuously without consulting a doctor.

It is important that you use the nasal spray regularly for the recommended treatment duration for full therapeutic benefit.

- If you forget to use it

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 use too much (overdose)

If you use more medicine than recommended, seek medical advice.

While you are using it

- Things you must do

The 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 so you will need to prepare the nasal spray following the instructions under 'Preparing the nasal spray'.

Preparing the nasal spray

You must prepare the nasal spray:

- Before you use it for the first time
- If you have not used it for a few days
- If you have just cleaned it following the instructions under 'Cleaning the nasal spray'.

Preparing the nasal spray helps to make sure you always get the full dose of medicine. Follow these steps:

- Shake the nasal spray and remove the dust cap. (picture 1)
- Hold the nasal spray upright and point the nozzle away from you.
- Put your forefinger and middle finger on the collar either side of the nozzle and put your thumb underneath the bottle. (picture 2)
- Keep your thumb still, and press down firmly on the collar with your fingers to release a fine spray into the air. (picture 2)
- The nasal spray is now ready to use.
- If you think the nozzle may be blocked, don't use a pin or anything sharp to clear it.
- Try to clean it by following the instructions under 'Cleaning the nasal spray'.



Picture 1

Picture 2

FLIXONASE AQUEOUS NASAL SPRAY

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Using the nasal spray

1. Shake the nasal spray and remove the dust cap.
2. Blow your nose to clear your nostrils.
3. Close one nostril with your finger and carefully place the nozzle in the other nostril. Tilt your head forward a little bit and hold the nasal spray upright. (picture 3a and 3b)
4. As you breathe in through your nose, press down firmly on the collar with your fingers. (picture 3a and 3b)
5. Breathe out through your mouth.
6. Repeat steps 3 to 4 for your other nostril.
7. After using your spray, wipe the nozzle carefully with a clean tissue or handkerchief.
8. Replace the dust cap. (picture 4)



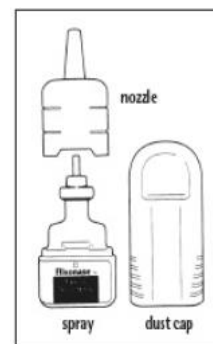
Picture 3a



Picture 3b



Picture 4



Picture 5

Cleaning the nasal spray

You must clean your nasal spray at least once a week to stop the nozzle from blocking up. Follow these steps:

- Remove the dust cap.
- Remove the nozzle by pulling upwards on the collar. (picture 5)
- Soak the nozzle and dust cap in warm water for a few minutes
- Then rinse under a running tap.
- Shake off the excess water and let them dry in a warm place.
- Put the nozzle back on the spray.

- Prepare the nasal spray following the instructions under 'Preparing the nasal spray' so that it is ready for use.

Things you must not do

Flixonase is only for use in the nose.

Things to be careful of

If after seven days:

- your symptoms have not improved, stop using the spray and speak to your doctor.
 - your symptoms have improved but not enough, speak to your doctor or pharmacist for advice.
- Fluticasone propionate is unlikely to produce an effect when handling machine or driving.
- Intranasal corticosteroids may cause children to grow more slowly. Children should use the recommended lowest dose and for the shortest duration.

Side Effects

When using this product you may experience nosebleeds, headache, unpleasant taste or smell, a dry or irritated throat or nose. Stop taking this medicine and tell your doctor immediately if:

- you experience an allergic reaction such as skin rashes and itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.
 - you get new changes to your vision that develop after starting this product. There have been very rare reports of eye problems such as cataracts or glaucoma in people who have used corticosteroids over a period of time.
 - you get small holes (perforations) in the ridge inside the nose that separates the nostrils.
- You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Flixonase

Storage

Store below 30°C. Shake gently before use.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines that are no longer required.

Product Description

What it looks like

Flixonase is an aqueous suspension of microfine fluticasone propionate for topical administration to the nasal mucous membrane by means of a metering, atomising spray pump. Pack size: 60 Units, 150 Units (Not all pack sizes may be marketed).

Ingredients

- Active ingredient:

Fluticasone Propionate

- Inactive ingredients:

Dextrose Anhydrous, Microcrystalline cellulose and carboxymethylcellulose sodium, Phenylethyl Alcohol, Benzalkonium chloride, Polysorbate 80, Dilute Hydrochloric Acid, Purified Water.

MAL number:

MAL20031743ACRZ

Manufacturer

Glaxo Wellcome S.A. Avenida De Extremadura 3, 09400 Aranda De Duero, Burgos, Spain

Product Registration Holder

Haleon Malaysia Sdn. Bhd. Lot 89, Jalan Enggang, Ampang/ Hulu Kelang Industrial Estate, 68000 Ampang, Selangor, Malaysia.

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