PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

FLIXONASE AQUEOUS NASAL SPRAY

50 µg/spray nasal spray, suspension

Fluticasone propionate

Read all of this leaflet carefully before you or your child start using FLIXONASE AQUEOUS NASAL SPRAY.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FLIXONASE AQUEOUS NASAL SPRAY has been prescribed for you or your child only. You should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What FLIXONASE AQUEOUS NASAL SPRAY is and what it is used for

FLIXONASE AQUEOUS NASAL SPRAY belongs to a group of medicines called corticosteroids.

FLIXONASE AQUEOUS NASAL SPRAY reduces inflammation in the nose and is used to treat symptoms which include:

- swelling and irritation in the nose
- blocked or runny nose
- sneezing and itchy nose.

FLIXONASE AQUEOUS NASAL SPRAY is used to prevent and treat inflammation in the lining of your nose (rhinitis) due to:

- seasonal allergies, such as hay fever
- all year round (perennial) allergies, such as animal allergies, house-dust mites or moulds.

2. What you need to know before you use FLIXONASE AQUEOUS NASAL SPRAY

Do not use FLIXONASE AQUEOUS NASAL SPRAY:

- if you or your child are allergic (hypersensitive) to fluticasone propionate or to any of the ingredients in FLIXONASE AQUEOUS NASAL SPRAY (listed in section 6 of this leaflet).

Warnings and precautions:

Before you or your child use FLIXONASE AQUEOUS NASAL SPRAY your doctor needs to know if you or your child:

- have an infection in your nose
- have an underactive adrenal gland
- are taking a medicine called ritonavir.

Check with your doctor if you think this may apply to you or your child.

Take special care with FLIXONASE AQUEOUS NASAL SPRAY:

- if you experience blurred vision or other visual disturbances, speak to your doctor.

Children and adolescents:

When using FLIXONASE AQUEOUS NASAL SPRAY for a long time, this may cause children to grow more slowly. The doctor will check your child's height regularly and make sure your child is taking the lowest possible dose.

FLIXONASE AQUEOUS NASAL SPRAY is only indicated for the short-term treatment of seasonal allergic rhinitis in children (4 – 11 years of age.

FLIXONASE AQUEOUS NASAL SPRAY is not indicated for use in children under 4 years of age.

Other medicine and FLIXONASE AQUEOUS NASAL SPRAY:

Always tell your health care provider if you are taking any other medicines. (This includes complementary or traditional medicines.)

Some medicines may affect how FLIXONASE AQUEOUS NASAL SPRAY works, or may increase the chance of having side effects. These medicines include:

- ritonavir (used to treat HIV)
- ketoconazole (used to treat fungal infections)

- steroids that you or your child have taken for a long time, either as an injection or by mouth.

Tell your doctor or pharmacist if you or your child are taking any of these.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice, before using FLIXONASE AQUEOUS NASAL SPRAY.

Driving and using machines:

It is not likely that FLIXONASE AQUEOUS NASAL SPRAY will affect your ability to drive or use machinery. However, do not drive or operate machinery, until you are certain that FLIXONASE AQUEOUS NASAL SPRAY has no effect.

FLIXONASE AQEOUS NASAL SPRAY contains benzalkonium chloride:

Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time.

3. How to use FLIXONASE AQUEOUS NASAL SPRAY

Do not share medicines prescribed for you with any other person.

Always use FLIXONASE AQUEOUS NASAL SPRAY exactly as your doctor has instructed you. You should check with your doctor if you are unsure.

FLIXONASE AQUEOUS NASAL SPRAY is sprayed into the nose as a fine mist.

The first time you use the spray, you must test that it is working properly.

Carefully follow the step-by-step instructions below.

Adults and children 12 years and over:

- The usual starting dose is 2 sprays into each nostril once a day, preferably in the morning
- If symptoms are very bad your doctor may increase the dose to a maximum of 2 sprays into each nostril twice a day (morning and evening) until the symptoms are under control

Once symptoms are controlled you may be able to reduce your dose to 2 sprays into each nostril, once a day. The maximum daily dose should not exceed two sprays into each nostril twice a day.

Children 4 to 11 years:

- The usual starting dose is 1 spray into each nostril once a day, preferably in the morning

If symptoms are very bad your doctor may increase this to one spray into each nostril twice a day (morning and evening) until the symptoms are under control. Your doctor may then reduce the dose to 1 spray into each nostril once a day. The maximum daily dose should not exceed two sprays into each nostril.

Step-by-step instructions (FLIXONASE AQUEOUS NASAL SPRAY in a glass bottle):

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'.



Picture 1



Picture 2

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

- Shake the nasal spray gently and remove the dust cap by gently squeezing the ribbed sides with your forefinger and thumb and pulling it straight off. Do not twist it off (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 for use.
- If you think the nozzle may be blocked, do not use a pin or anything sharp to clear it.

- Try to clean it by following the instructions under ‘Cleaning the nasal spray’.

Using the nasal spray:

Picture 3a



Picture 3b



Picture 4



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.

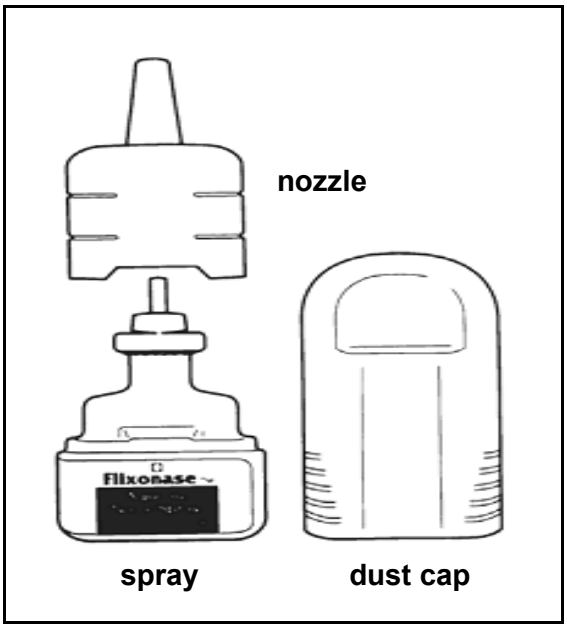
7. After using your spray, wipe the nozzle carefully with a clean tissue or handkerchief.

8. Replace the dust cap (picture 4).

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 the nozzle and dust cap dry in a warm place.



Picture 5

- 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.

Step-by-step instructions (FLIXONASE AQUEOUS NASAL SPRAY in a plastic bottle):

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'.

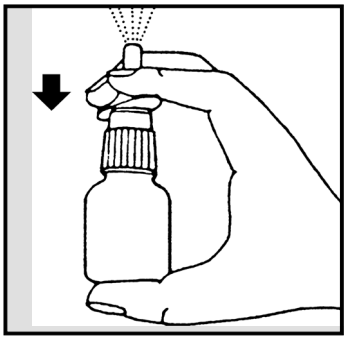
Preparing the nasal spray:

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’.



Picture 1



Picture 2

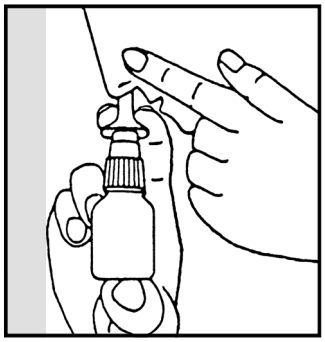
Preparing the nasal spray helps to make sure you always get the full dose of medicine. Follow these steps:

- Shake the nasal spray gently and remove the dust cap by gently squeezing the ribbed sides with your forefinger and thumb and pulling it straight off. Do not twist it off (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 for use.

- If you think the nozzle may be blocked, do not use a pin or anything sharp to clear it.
- Try to clean it by following the instructions under ‘Cleaning the nasal spray’.

Using the nasal spray:

Picture 3a



Picture 3b



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.
9. Replace the cap.

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.
- Soak the nozzle and cap in warm water for a few minutes.
- Then rinse under a running tap.
- Shake off the excess water and let the nozzle and cap 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.

If you use more FLIXONASE AQUEOUS NASAL SPRAY than you should:

If you use more FLIXONASE AQUEOUS NASAL SPRAY and are also taking other steroid (cortisone) treatment, you may decrease the activity of your adrenal gland.

If you use too much FLIXONASE AQUEOUS NASAL SPRAY, contact your doctor or pharmacist for advice. If possible, show them the FLIXONASE AQUEOUS NASAL SPRAY pack.

If you forget to use FLIXONASE AQUEOUS NASAL SPRAY

If you miss a dose FLIXONASE AQUEOUS NASAL SPRAY, use it when you remember. If it is nearly time for your next dose, wait until then.

Do not use an extra dose to make up for a missed dose. Just take your next dose at the usual time.

Effects when treatment with FLIXONASE AQUEOUS NASAL SPRAY is stopped:

It may take three to four days for FLIXONASE AQUEOUS NASAL SPRAY to work fully and it is important that you use FLIXONASE AQUEOUS NASAL SPRAY regularly.

Use FLIXONASE AQUEOUS NASAL SPRAY for as long as your doctor recommends. Do not stop unless your doctor advises you to.

4. Possible side effects

FLIXONASE AQUEOUS NASAL SPRAY can have side effects.

Not all side effects reported for FLIXONASE AQUEOUS NASAL SPRAY are include in this leaflet. Should your general health worsen, or if you experience any untoward effects while using FLIXONASE AQUEOUS NASAL SPRAY, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using FLIXONASE AQUEOUS NASAL SPRAY and tell your doctor immediately, or go to the causualty department at your nearest hospital:

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

These are all very serious side effects. If you or your child have them, you may have had a serious reaction to FLIXONASE AQUEOUS NASAL SPRAY. You or your child may need urgent medical attention or hospitalisation.

Tell your doctor immedeately or go to the casualty department at your nearest hospital if you notice any of the following:

- cloudy lens in the eye (cataract), increased pressure of the eye that causes problems with vision (glaucoma). These eye problems occurred in people who used FLIXONASE AQUEOUS NASAL SPRAY for a long time
- small holes (perforations) in the ridge inside the nose that separates the nostrils.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache, unpleasant taste and/or smell
- nose bleeds; a dry or irritated throat or nose – you may also get streaks of blood when you blow your nose.

Other side effects with an unknown frequency that may occur, include:

- sores in the nose.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FLIXONASE AQUEOUS NASAL SPRAY.

5. How to store FLIXONASE AQUEOUS NASAL SPRAY

Store all unused medicine out of reach of children.

Store at or below 30 °C.

Keep in original package to protect from light.

Do not use after the expiry date shown on the pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FLIXONASE AQUEOUS NASAL SPRAY contains:

The active ingredient is fluticasone propionate.

Each 100 mg spray of FLIXONASE AQUEOUS NASAL SPRAY contains 50 µg (microgram) of fluticasone propionate.

The spray also contains benzalkonium chloride 0,02 % *m/m* and phenylethyl alcohol 0,25 % *m/m* as preservatives.
The other ingredients are carboxymethylcellulose sodium, dextrose (anhydrous), diluted hydrochloric acid, microcrystalline cellulose, polysorbate 80 and purified water.

What FLIXONASE AQUEOUS NASAL SPRAY looks like and contents of the pack:

A white suspension.

FLIXONASE AQUEOUS NASAL SPRAY is available in an amber glass bottle or a white plastic bottle fitted with a metering, atomising pump, nasal adaptor and a dust cover. Each bottle provides approximately 120 metered sprays, when used as recommended.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd
39 Hawkins Avenue
Epping Industria 1, 7460

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