PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

FLIXONASE NASULES

400 micrograms/dose nasal drops, suspension

Fluticasone propionate

Read all of this leaflet carefully before you start using FLIXONASE NASULES.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.
- FLIXONASE NASULES have been prescribed for you and 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 NASULES are and what it is used for
2. What you need to know before you use FLIXONASE NASULES
3. How to use FLIXONASE NASULES
4. Possible side effects

5. How to store FLIXONASE NASULES

6. Contents of the pack and other information

1. What FLIXONASE NASULES are and what is it used for

FLIXONASE NASULES belong to a group of medicines called corticosteroids.

FLIXONASE NASULES reduce inflammation in the nose and are used to treat symptoms which include:

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

FLIXONASE NASULES are used to treat:

- small growths inside the nose (polyps)
- symptoms associated with nasal obstruction.

2. What you need to know before you use FLIXONASE NASULES

Do not use FLIXONASE NASULES:

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

Warnings and precautions:

Before you use FLIXONASE NASULES, your doctor needs to know if you:

- 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.

Take special care with FLIXONASE NASULES:

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

Children and adolescents:

When using FLIXONASE NASULES 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 NASULES are only indicated for use in adolescents aged 16 years or older and should not be used by children or adolescents younger than 16 years of age.

Other medicines and FLIXONASE NASULES:

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 NASULES work, 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 have taken for a long time, either as an injection or by mouth.

Tell your doctor or pharmacist if you 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 NASULES.

Driving and using machines:

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

3. How to use FLIXONASE NASULES

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

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

FLIXONASE NASULES are supplied in a strip of plastic containers.

Each plastic container is for single-use only.

Adults and adolescents over 16 years of age:

- The usual dose is one single-use plastic container, once or twice daily.
- Divide the dose equally between each nostril.

As your symptoms improve, your doctor may ask you to use a lower dose.

Contact your doctor if your symptoms get worse or do not improve after several weeks.

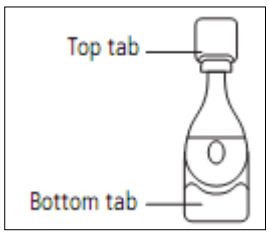
FLIXONASE NASULES should only be used in the nose.

Your doctor will monitor your condition regularly.

Carefully follow the step-by-step instructions below.

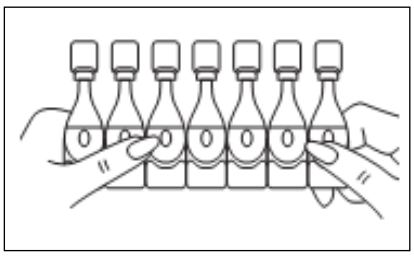
Step-by-step instructions:

What the plastic container looks like:

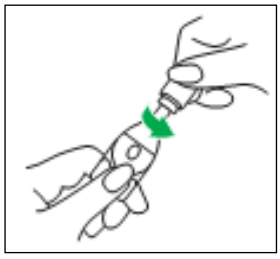


Using your FLIXONASE NASULES nasal drops:

Picture a



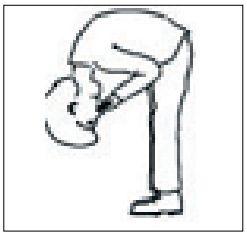
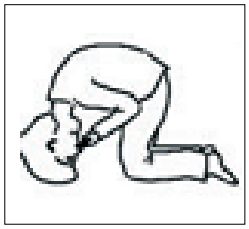
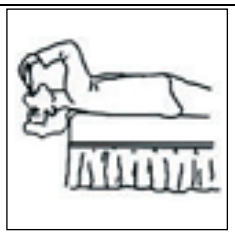
Picture b



1. Open the foil pack by tearing off one side. Do not open the pack until the drops are needed.
2. Take out the strip of plastic containers from the foil and pull off one container. **(Picture a)**
3. Put the remaining containers back into the foil pack and put the pack back in the box.
4. Flick and shake the plastic container several times. The contents of the container **must be well mixed** before use.
5. Then shake downwards to make sure the liquid is not in the neck of the container.
6. Hold the bottom tab of the container firmly. Twist and remove the top tab to open it. **(Picture b)**

How to put the drops in:

Before you put the drops in, you must choose one of the positions shown in these pictures. Although they may not be easy, the positions will make sure the drops get to where they are needed.

Position 1	**Position 2**	**Position 3**
		

1. Gently blow your nose to clear it.
2. While standing up, bend right over **(Position 1).**

3. If you cannot do this, kneel down and then bend right over **(Position 2).**
4. Put the opened container into one nostril and gently squeeze.
5. Keep squeezing until the sides of the container touch each other. This will mean that about half the dose has been given (about 6 drops).
6. Repeat this step to use the rest of the remaining dose in your other nostril.
7. Stay with your head down for at least one minute after putting the drops in.

If these positions are difficult you can lie on a bed with your head tilted over the edge **Position 3).**

After you have put the drops in, rest your head sideways on the bed for at least one minute.

If you use more FLIXONASE NASULES than you should:

If you use too many FLIXONASE NASULES, contact your doctor or pharmacist for advice. If possible, show them the FLIXONASE NASULE pack.

If you forget to use FLIXONASE NASULES:

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

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

Effects when treatment with FLIXONASE NASULES are stopped:

It may take several weeks for FLIXONASE NASULES to work fully and it is important that you use FLIXONASE NASULES regularly.

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

4. Possible side effects

FLIXONASE NASULES can have side effects.

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

If any of the following happens, stop using FLIXONASE NASULES 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 have them, you may have had a serious allergic reaction to FLIXONASE NASULES. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately 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 NASULES 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 NASULES.

5. How to store FLIXONASE NASULES

Store all unused medicine out of reach of children.

Store at or below 30 °C.

Store upright.

Keep in original package to protect from light.

Do not freeze.

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 NASULES contain:

The active ingredient is fluticasone propionate.

FLIXONASE NASULES are an aqueous suspension of fluticasone propionate presented in polyethylene containers. Each container holds 400 microgram (µg) of fluticasone propionate.

The other ingredients are dibasic sodium phosphate anhydrous, sodium dihydrogen phosphate dihydrate, polysorbate 20, sodium chloride, sorbitan laurate and water for injections.

What FLIXONASE NASULES looks like and contents of the pack:

A white, opaque suspension.

FLIXONASE NASULES are presented in polyethylene containers.

These containers are packed as a strip of 7 units within a foil wrapper.

FLIXONASE NASULES are available as 4 strips of 7 units.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

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