SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

FLIXONASE NASULES 400 micrograms/dose, nasal drops suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal drops, suspension.

A white, opaque suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults and adolescents over 16 years of age:

FLIXONASE NASULES are indicated for the regular treatment of small to medium sized nasal polyps and associated symptoms of nasal obstruction.

4.2 Posology and method of administration

Posology

Diagnosis should be confirmed by a specialist.

For full therapeutic benefit regular usage is essential. The absence of an immediate effect should be explained to the patient as maximum relief may not be obtained until after several weeks of treatment. However, if no improvement in symptoms is seen after four to six weeks, alternate therapies should be considered.

Nasal polyps require regular medical assessment to monitor severity of the condition.

Adults and adolescents over 16 years of age:

The contents of one container (400 µg) to be instilled into the nose once or twice daily. The dose should be divided between the affected nostrils.

The elderly:

The normal adult dosage is applicable.

Children:

There are insufficient data at present to recommend the use of fluticasone propionate for the treatment of nasal polyps in children.

Unilateral polyposis rarely occurs, and could be indicative of other conditions.

Method of administration

FLIXONASE NASULES are for administration by the intranasal route only. Contact with the eyes should be avoided.

4.3 Contraindications

FLIXONASE NASULES are contraindicated in patients with a hypersensitivity to fluticasone propionate or to any of the ingredients listed in section 6.1.

4.4 Special warnings and precautions for use

Infections of the nasal airways should be appropriately treated but do not constitute a specific contraindication to treatment with FLIXONASE NASULES.

The full benefit of FLIXONASE NASULES may not be achieved until treatment has been administered for several weeks.

Care must be taken while transferring patients from systemic steroid treatment and commencing therapy with FLIXONASE NASULES if there is any reason to suppose that their adrenal function is impaired.

FLIXONASE NASULES may cause hypothalamic-pituitary-adrenal (HPA) axis suppression following intranasal application at dosages higher than recommended.

Systemic effects with nasal corticosteroids have been reported, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations.

Reduced growth velocity has been observed in children treated with intranasal corticosteroids. Therefore, children should be maintained on the lowest dose which achieves adequate symptom control.

During post-marketing use, there have been reports of clinically significant interactions in patients receiving FLIXONASE NASULES and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of FLIXONASE NASULES and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects (see section 4.5).

Visual disturbance has been reported by patients using systemic and/or topical corticosteroids. If a patient has blurred vision or other visual disturbances, consider evaluation of possible causes which may include cataract, glaucoma or central serous chorioretinopathy.

4.5 Interaction with other medicines and other forms of interaction

Under normal circumstances, very low plasma concentrations of fluticasone propionate are achieved after intranasal dosing, due to extensive first pass metabolism and high systemic clearance mediated by cytochrome P450 3A4 in the gut and liver. Hence, clinically significant interactions mediated by fluticasone propionate are unlikely.

An interaction study in healthy subjects has shown that ritonavir (a highly potent cytochrome P450 3A4 inhibitor) can greatly increase fluticasone propionate plasma concentrations, resulting in markedly reduced serum cortisol concentrations. During post-marketing use, there have been reports of clinically significant interactions in patients receiving FLIXONASE NASULES and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of FLIXONASE NASULES and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects.

Studies have shown that other inhibitors of cytochrome P450 3A4 produce negligible (erythromycin) and minor (ketoconazole) increases in systemic exposure to fluticasone propionate without notable reductions in serum cortisol concentrations. Nevertheless, care is advised when co-administering potent cytochrome P450 3A4 inhibitors (e.g. ketoconazole), as there is potential for increased systemic exposure to fluticasone propionate.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. Corticosteroids have been shown to be teratogenic in animals. As these medicines may be absorbed systemically when administered intra-nasally, teratogenicity cannot be excluded.

4.7 Ability to drive and use machines

FLIXONASE NASULES are unlikely to produce an effect.

4.8 Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 and < 1/10), uncommon (≥ 1/1 000 and < 1/100), rare (≥ 1/10 000 and < 1/1 000) and very rare (< 1/10 000) including isolated reports and not known (cannot be estimated from the available data).

Clinical trial data

Nervous system disorders:

Common: headache, unpleasant taste, unpleasant smell.

As with other nasal preparations, unpleasant taste and smell and headache have been reported.

Respiratory, thoracic and mediastinal disorders:

Very common: epistaxis

Common: nasal dryness, nasal irritation, throat dryness, throat irritation.

Post-marketing data

Immune system disorders:

Very rare: hypersensitivity, anaphylaxis/anaphylactoid reactions, bronchospasms, skin rash, oedema of the face or tongue.

Eye disorders:

Very rare: glaucoma, raised intraocular pressure, cataract

Respiratory, thoracic and mediastinal disorders:

Very rare: nasal septal perforation

Not known: nasal ulcers.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of FLIXONASE NASULES is important. It allows continued monitoring of the benefit/risk balance of FLIXONASE NASULES. Health care providers are asked to report any suspected adverse reactions 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.

4.9 Overdose

See section 4.8.

Chronic - Administration of fluticasone propionate in daily doses in excess of that recommended, or in conjunction with other corticosteroid formulations, may lead to some degree of suppression of hypothalamic-pituitary-adrenal function. Monitoring of adrenal reserve may be indicated.

Further treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 21.5.1 Corticosteroids and analogues.

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use.

Corticosteroids.

ATC code: R01AD08.

Fluticasone propionate has anti-inflammatory activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dibasic sodium phosphate anhydrous

Sodium dihydrogen phosphate dihydrate

Polysorbate 20

Sodium chloride

Sorbitan laurate

Water for injections.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at or below 30 °C.

Store upright.

Protect from light.

Do not freeze.

6.5 Nature and contents of container

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

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

FLIXONASE NASULES are available as 4 strips of 7 units.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

8. REGISTRATION NUMBER

33/21.5.1/0329

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 September 2000

10. DATE OF REVISION OF THE TEXT

6 December 2020

GDS-29

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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.

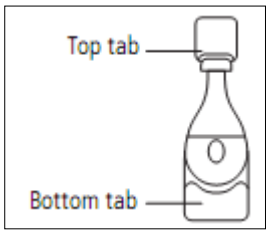
FLIXONASE NASULES should only be used in the nose.

Your doctor will monitor your condition regularly.

Carefully follow the step-by-step instructions below.

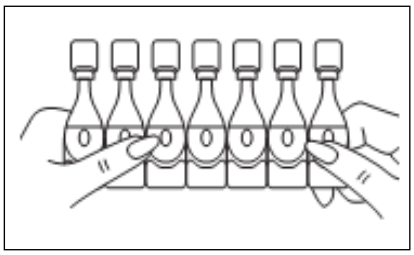
Step-by-step instructions:

What the plastic container looks like:

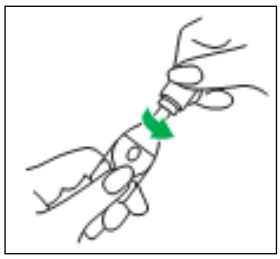


Using your FLIXONASE NASULES nasal drops:

Picture a



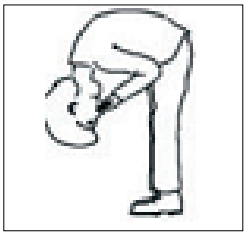
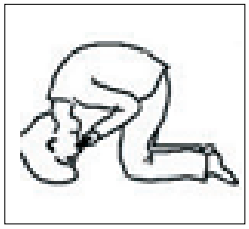
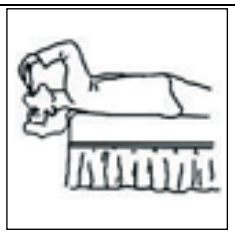
Picture b



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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6 December 2020

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Date of registration:

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