GENEMIST

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

GENEMIST 27,5 µg/spray, nasal spray suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 50 µl spray contains 27,5 µg of fluticasone furoate.

Preservatives: benzalkonium chloride 0,015 % *m/m* and disodium edetate 0,015 % *m/m.*

Excipient with known effect:

Benzalkonium chloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, suspension.

A white uniform suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults and adolescents (12 years and over):

Treatment of the symptoms of seasonal allergic rhinitis:

In patients with seasonal allergic rhinitis, GENEMIST nasal spray is indicated in the treatment of nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing) and ocular symptoms (itching/burning, tearing/watering, and redness of the eye).

Treatment of the symptoms of perennial allergic rhinitis:

In patients with perennial allergic rhinitis, GENEMIST nasal spray is indicated in the treatment of nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing).

Children (2 to 11 years):

Treatment of the symptoms of seasonal allergic rhinitis:

In patients with seasonal allergic rhinitis, GENEMIST nasal spray is indicated in the treatment of nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing).

Treatment of the symptoms of perennial allergic rhinitis:

In patients with perennial allergic rhinitis, GENEMIST nasal spray is indicated in the treatment of nasal symptoms (rhinorrhoea, nasal congestion, nasal itching and sneezing).

4.2 Posology and method of administration

Posology

For full therapeutic benefit regular scheduled usage is recommended. Onset of action has been observed as early as 8 hours after initial administration. It may take several days of treatment to achieve maximum benefit. An absence of an immediate effect should be explained to the patient.

Seasonal allergic rhinitis and perennial allergic rhinitis:

Adults and adolescents (12 years and over):

The recommended starting dosage is two sprays (27,5 µg of fluticasone furoate per spray) in each nostril once daily (total daily dose: 110 µg).

Once adequate control of symptoms is achieved, dose reduction to one spray in each nostril (total daily dose: 55 µg) may be effective for maintenance.

Children (2 to 11 years of age):

The recommended starting dosage is one spray (27,5 µg of fluticasone furoate per spray) in each nostril once daily (total daily dose: 55 µg).

Patients not adequately responding to one spray in each nostril once daily (total daily dose: 55 µg) may use two sprays in each nostril once daily (total daily dose: 110 µg). Once adequate control of symptoms is achieved, dose reduction to one spray in each nostril once daily (total daily dose: 55 µg) is recommended.

Children under 2 years of age: There is no experience in children under the age of 2 years.

Elderly patients: The normal adult dosage is applicable.

Renal patients: The normal adult dosage is applicable.

Hepatic patients: No dose adjustment is required in patients with hepatic impairment (see section 5.2).

Method of administration:

GENEMIST nasal spray is for administration by the intranasal route only.

Shake the nasal spray before use.

Patients should be instructed that the device must be primed before first use and re-primed if the cap is left off or the device does not seem to be working. In order to prime the device the nasal spray needs to be shaken vigorously for about 10 seconds with the cap on.
This is important as fluticasone furoate is a thick suspension that becomes liquid when vigorously shaken. It will only spray when it becomes liquid. The patient must then press the button firmly all the way in, approximately 6 times until a fine mist is seen, to ensure a full dose is delivered. Once primed the patient must shake the nasal spray vigorously each time before use. The cap must be replaced after use to keep the nozzle clean and to prevent the need for re-priming.

4.3 Contraindications

Hypersensitivity to fluticasone furoate or to any of the excipients of GENEMIST nasal spray listed in section 6.1.

4.4 Special warnings and precautions for use

If there is any reason to suppose that adrenal function is impaired, care must be taken when transferring patients from systemic steroid treatment to fluticasone furoate.
Fluticasone furoate has a negligible (0,50 %) systemic bioavailability at intranasal doses of up to 24 times the recommended adult daily dose (2 640 µg per day). Systemic effects of nasal corticosteroid may occur, particularly at high doses prescribed for prolonged periods. These effects are less likely to occur than with oral corticosteroids and may vary between patients and different corticosteroids.
Treatment with higher than recommended doses of nasal corticosteroids may result in clinically significant adrenal suppression. If there is evidence for higher than recommended

doses being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery. Fluticasone furoate once daily was not associated with HPA axis suppression in adult, adolescent or paediatric subjects.

However the dose of intranasal fluticasone furoate should be reduced to the lowest dose at which effective control of the symptoms of rhinitis are maintained.

Growth retardation has been reported in children receiving some nasal corticosteroids at licensed doses. A reduction in growth velocity has been observed in children treated with fluticasone furoate 110 µg daily for one year (see section 4.8). Therefore, children should be maintained on the lowest dose which delivers adequate symptom control (see section 4.2).

It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring the patient to a paediatric specialist.

Medical practioners should be alert to the risk that potential systemic steroid effects including ocular changes, such as central serous chorioretinopathy may occur.

GENEMIST contains benzalkonium chloride (see section 6.1). Long-term use may cause oedema of the nasal mucosa.

4.5 Interaction with other medicines and other forms of interaction

Fluticasone furoate is rapidly cleared by extensive first pass metabolism mediated by the cytochrome P450 3A4. In an interaction study of intranasal fluticasone furoate with the potent CYP3A4 inhibitor ketoconazole, there were more subjects with measurable fluticasone furoate concentrations in the ketoconazole group (6 of the 20 subjects) compared to placebo (1 out of 20 subjects). This small increase in exposure did not result in statistically significant difference in 24 hour serum cortisol levels between the two groups.

Based on data with another glucocorticoid metabolised by CYP3A4, co-administration with ritonavir is not recommended because of the risk of increased systemic exposure of fluticasone furoate.

The enzyme induction and inhibition data suggest that there is no theoretical basis for anticipating metabolic interactions between fluticasone furoate and the cytochrome P450 mediated metabolism of other compounds at clinically relevant intranasal doses. Therefore, no clinical studies have been conducted to investigate interactions of fluticasone furoate on other medicines.

4.6 Fertility, pregnancy and lactation

Safety and efficacy of GENEMIST in pregnancy and lactation has not been established.

There are no fertility data in humans.

4.7 Effects on ability to drive and use machines

Based on the pharmacology of fluticasone furoate and other intranasally administered steroids, there is no reason to expect an effect on ability to drive or to operate machinery with GENEMIST.

4.8 Undesirable effects

Data from large clinical trials were used to determine the frequency of adverse reactions.

The following convention has been used for the classification of frequency:

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, very rare <1/10 000, not known (cannot be estimated from the available data).

Clinical trial data:

Respiratory, thoracic and mediastinal disorders	
Very common	Epistaxis
Common	Nasal ulceration
Musculoskeletal and connective tissue disorders	
Not known	Growth retardation in children
Eye disorders	
Not known	Vision blurred (see section 4.4)

Description of selected adverse reactions:

Epistaxis:

Epistaxis was generally mild to moderate in intensity. In adults and adolescents, the incidence of epistaxis was higher in longer-term use (more than 6 weeks) than in short-term use (up to 6 weeks). In paediatric clinical studies of up to 12 weeks duration the incidence of epistaxis was similar between patients receiving fluticasone furoate and patients receiving placebo.

Growth retardation:

In a one-year clinical study assessing growth in pre-pubescent children receiving 110 µg of GENEMIST once daily, an average treatment difference of -0,27 cm per year in growth velocity was observed compared to placebo.

Post-marketing data:

Immune system disorders:

Rare: hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria

Nervous system disorders:

Common: headache

Respiratory, thoracic and mediastinal disorders:

Uncommon: rhinalgia, nasal discomfort (including nasal burning, nasal irritation, and nasal soreness), nasal dryness

Very rare: nasal septum perforation.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of GENEMIST is important. It allows continued monitoring of the benefit/risk balance of GENEMIST. 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

In a bioavailability study, intranasal doses of up to 2 640 µg per day were administered over three days with no adverse systemic effects observed. Acute overdose is unlikely to require any therapy other than observation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 21.5.1 Corticosteroids and analogues.

Pharmacotherapeutic group: Nasal preparations, corticosteroids.

ATC code: R01AD12.

Fluticasone furoate is a synthetic trifluorinated corticosteroid that possesses a high affinity for the glucocorticoid receptor and has a potent anti-inflammatory action.

5.2 Pharmacokinetic properties

Absorption: Fluticasone furoate undergoes incomplete absorption and extensive first-pass metabolism in the liver and gut resulting in negligible systemic exposure. The intranasal dosing of 110 µg once daily does not typically result in measurable plasma concentrations (< 10 ug/ml). The absolute bioavailability for intranasal fluticasone furoate administered as 880 µg three times per day (2 640 µg total daily dose) is 0,50 %.

Distribution: The plasma protein binding of fluticasone furoate is greater than 99 %. Fluticasone furoate is widely distributed with volume of distribution at steady-state of, on average, 608 L.

Metabolism: Fluticasone furoate is rapidly cleared (total plasma clearance of 58,7 L/h) from systemic circulation principally by hepatic metabolism to an inactive 17β-carboxylic metabolite (GW694301X), by the cytochrome P450 enzyme CYP3A4. The principal route of metabolism was hydrolysis of the S-fluoromethyl carbothioate function to form the 17β-carboxylic acid metabolite. *In vivo* studies have revealed no evidence of cleavage of the furoate moiety to form fluticasone.

Elimination: Elimination was primarily via the faecal route following oral and intravenous administration indicative of excretion of fluticasone furoate and its metabolites via the bile. Following intravenous administration, the elimination phase half-life averaged 15,1 hours. Urinary excretion accounted for approximately 1 % and 2 % of the orally and intravenously administered dose, respectively.

Children:

Fluticasone furoate is typically not quantifiable (< 10 ug/mL) following intranasal dosing of 110 µg once daily. Quantifiable levels were observed in < 16 % of paediatric patients following intranasal dosing of 110 µg once daily and only < 7 % of paediatric patients

following 55 µg once daily. There was no evidence for a higher incidence of quantifiable levels of fluticasone furoate in younger children (less than 6 years of age).

Elderly:

Only a small number of elderly subjects (n = 23/872; 2,6 %) provided pharmacokinetic data. There was no evidence for a higher incidence of subjects with quantifiable fluticasone furoate concentrations in the elderly, when compared with the younger subjects.

Renal impairment:

Fluticasone furoate is not detectable in urine from healthy volunteers after intranasal dosing. Less than 1 % of dose-related material is excreted in urine and therefore renal impairment would not be expected to affect the pharmacokinetics of fluticasone furoate.

Hepatic impairment:

There are no data on intranasal fluticasone furoate in subjects with hepatic impairment. Data are available following inhaled administration of fluticasone furoate (as fluticasone furoate or fluticasone furoate/vilanterol) to subjects with hepatic impairment that are also applicable for intranasal dosing. A study of a single 400 µg dose of oral inhaled fluticasone furoate in patients with moderate hepatic impairment (Child-Pugh B) resulted in increased C_{max} (42 %) and $AUC_{(0-\infty)}$ (172 %) compared to healthy subjects. Following repeat dosing of orally inhaled fluticasone furoate/vilanterol for 7 days, there was an increase in fluticasone furoate systemic exposure (on average two-fold as measured by $AUC_{(0-24)}$) in subjects with moderate or severe hepatic impairment (Child-Pugh B or C) compared with healthy subjects. The increase in fluticasone furoate systemic exposure in subjects with moderate hepatic impairment (fluticasone furoate/vilanterol 200/25 µg) was associated with an average 34 % reduction in serum cortisol compared with healthy subjects. There was no effect on serum

cortisol in subjects with severe hepatic impairment (fluticasone furoate/vilanterol 100/12,5 µg). Based on these findings the average predicted exposure for 110 µg of intranasal fluticasone furoate in this patient population would not be expected to result in suppression of cortisol.

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose anhydrous

Dispersible cellulose

Polysorbate 80

Purified water

Benzalkonium chloride

Disodium edetate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 30 ºC in the container specified.

Do not refrigerate or freeze.

6.5 Nature and contents of container

The nasal spray container consists of an inner container within an outer device. The inner container consists of a Type I or Type III amber glass bottle, closed with a metering spray pump. The outer device is a predominantly off-white side-actuated plastic delivery system with a light blue lever and lid containing a stopper. The outer plastic cover has a window for viewing the bottle contents.

GENEMIST is available in three pack sizes:

- 30 sprays with a target net content of 4,5 g
- 60 sprays with a target net content of 6,5 g
- 120 sprays with a target net content of 10 g**.**

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. HOLDER OF CERTIFICATE OF REGISTRATION

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

8. REGISTRATION NUMBER

41/21.5.1/0967

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 June 2009

10. DATE OF REVISION OF THE TEXT

18 March 2021

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

GENEMIST 27,5 µg/spray, nasal spray suspension

Fluticasone furoate

Read all of this leaflet carefully before you start using GENEMIST.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- GENEMIST has been prescribed for you personally 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 GENEMIST is and what it is used for

GENEMIST contains the medicine fluticasone furoate. It is a steroid which helps decrease inflammation in the nose and irritation of the eyes caused by allergies (rhinitis). The effects are usually felt within the first day, although some people will not feel the full effects until several days after first using GENEMIST.

The doctor has prescribed GENEMIST to help treat symptoms caused by allergies, including watery and itchy eyes, stuffy or runny nose, and sneezing. Symptoms can occur at specific times of the year and be caused by allergies to pollen from grass or trees (hayfever) or they can occur all year around and be caused by allergies to animals, dust; house-dust mites or moulds. Using GENEMIST once daily will help prevent both daytime and night time symptoms.

GENEMIST is delivered into the nose as a fine mist spray. GENEMIST is not for use in the eyes. There is a window on the side of the outer plastic cover of GENEMIST so that you can see how much medicine is left in the nasal spray bottle. Ask your doctor for more medicine when the amount of medicine left is getting low.

2. What you need to know before you use GENEMIST

Do not use GENEMIST if:

You are allergic (hypersensitive) to fluticasone furoate or any of the other ingredients of GENEMIST (listed in section 6 of this leaflet).

Warnings and precautions:

Tell your doctor or health care provider, before using GENEMIST if you or your child:

- Nasal corticosteroids can affect the normal production of hormones in your body, particularly if you use high doses for a long time

Take special care with GENEMIST:

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

Children and adolescents:

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

GENEMIST is not recommended for use in children below 2 years of age.

Other medicine and GENEMIST:

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

Some medicines may affect how GENEMIST works, or make it more likely that you will have side effects.

Tell your doctor or pharmacist if you are taking:

- medicines for asthma
- any medicines containing a steroid. These may include some eczema creams, injections, tablets, nasal sprays and eye or nose drops
- ritonavir (a medicine used in the treatment of HIV)
- ketoconazole (a medicine used to treat fungal infections).

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 GENEMIST.

Driving and using machines:

GENEMIST is unlikely to affect your ability to drive and use machines.

GENEMIST contains benzalkonium chloride:

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

3. How to use GENEMIST

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

Always use GENEMIST exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Use your GENEMIST once every day as close to the same time of day as possible, to treat your symptoms throughout the day and night.

GENEMIST is sprayed into the nose as a fine mist.

Adults and adolescents 12 years and older:

The usual starting dose is 2 sprays in each nostril once every day.

Once symptoms are controlled you may be able to decrease your dose to 1 spray in each nostril once every day.

Children (2 to 11 years of age):

In children aged 2 to 11 years the usual starting dose is 1 spray in each nostril once every day.

If symptoms are very bad the doctor may increase the dose to 2 sprays in each nostril once every day until symptoms are under control. It may then be possible for the dose to be reduced to 1 spray in each nostril once every day.

If you have the impression that the effect of GENEMIST is too strong or too weak, tell your doctor or pharmacist.

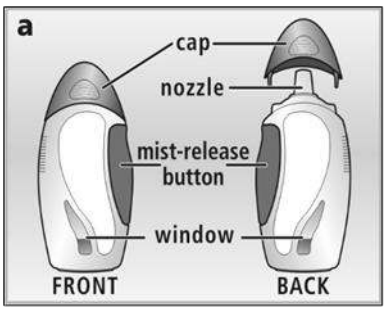
Instructions for use:

This section includes the following information:

- The nasal spray
- Six important things you need to know about GENEMIST
- Preparing the nasal spray
- Using the nasal spray
- Cleaning the nasal spray.

The nasal spray:

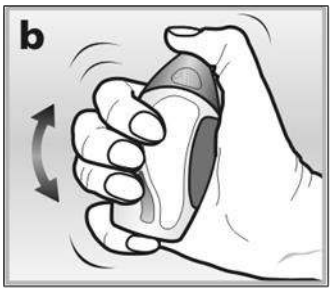
- GENEMIST comes in a brown glass bottle inside a plastic casing. It will contain either 30, 60 or 120 sprays, depending on the pack size that has been prescribed for you. **(picture a).**
- A window in the plastic casing allows you to see how much medicine is left. You will be able to see the liquid level for a new 30 or 60 spray bottle (**picture a**), but not for a new 120 spray bottle because the liquid level is above the window.



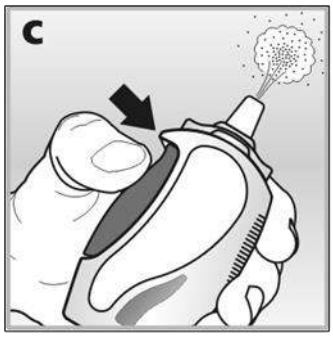
- The medicine sprays out of the nozzle when the button on the side is pressed firmly all the way in.
- A removable cap protects the nozzle from dust and prevents it from blocking up.

Six important things you need to know about GENEMIST:

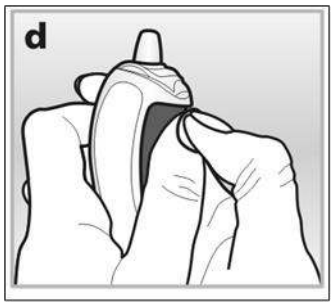
1. The nasal spray comes in a brown glass bottle. To check how much is left, **hold the nasal spray upright against a bright light**. You will then be able to see the level through the window.
2. When you **first use the nasal spray you must shake it vigorously** with the cap on for about 10 seconds. This is important as GENEMIST is very thick and becomes more liquid when you shake it well (**picture b**). It will only spray when it becomes liquid.



3. The button on the side must be pressed firmly all the way in, to release a spray through the nozzle (**picture c**).



4. If you have difficulty pressing the button with your thumb, you can use two hands (**picture d**).



5. **Always keep the cap on the nasal spray** when you are not using it. The cap keeps the dust out, seals in the pressure and stops the nozzle from blocking up. When the cap is in place, the button on the side cannot be pressed accidentally.
6. **Never use a pin** or anything sharp to clear the nozzle. It will damage the nasal spray.

Preparing the nasal spray:

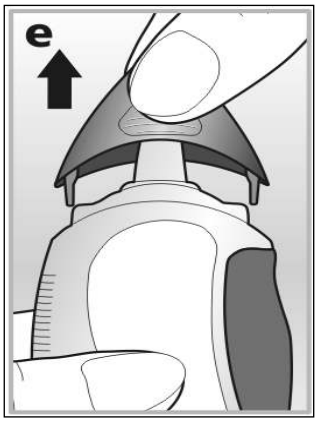
You must prepare the nasal spray:

- before you use it for the first time
- if you have left the cap off.

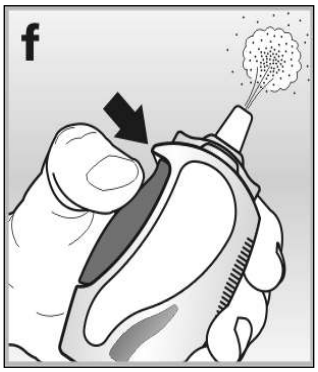
Preparing the nasal spray helps to make sure you always get the full dose of medicine.

Follow these steps:

- With the cap on, **shake the nasal spray vigorously** for about 10 seconds.
- Remove the cap by gently squeezing the sides of the cap with your thumb and forefinger and pulling it straight off **(picture e)**.



- Hold the nasal spray upright and point the nozzle away from you.
- **Press the button firmly all the way in. Do this at least 6 times** to release a fine spray into the air **(picture f)**.



The nasal spray is now ready for use.

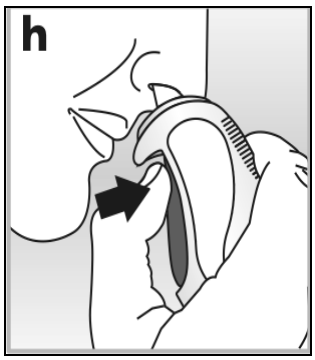
Using the nasal spray:

1. **Shake the nasal spray vigorously.**
2. Remove the cap.
3. **Blow your nose** to clear your nostrils, and then tilt your head forward a little bit.
4. Hold the nasal spray upright and carefully place the nozzle in one of your nostrils **(picture g)**.

5. Point the end of the nozzle toward the outside of your nose, away from the centre ridge of your nose

   This helps direct the medicine to the right part of your nose.

6. As you breathe in through your nose, **press the button once firmly all the way in (picture h)**.

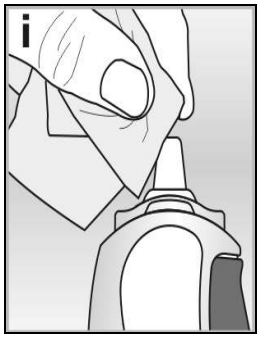


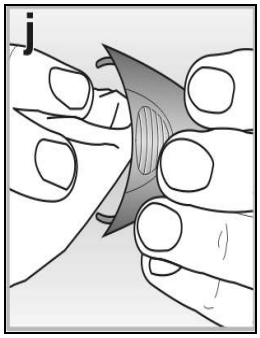
7. Be careful not to get any spray in your eyes. If you do, rinse your eyes with water.
8. Take the nozzle out and breathe out through your mouth.
9. If your doctor has told you to take two sprays per nostril, repeat steps 4 to 6.
10. Repeat steps 4 to 6 for your other nostril.
11. **Replace the cap** on the nasal spray.

Cleaning the nasal spray:

After each use:

- Wipe the nozzle and the inside of the cap **(picture i and j)**. Do not use water to do this. Wipe with a clean, dry tissue.





- **Never use a pin** or anything sharp on the nozzle.
- **Always replace the cap** once you have finished, to keep out dust, seal in the pressure and stop the nozzle from blocking up.

If the nasal spray does not seem to be working:

- Check you still have medicine left. Look at the level through the window. If the level is very low there may not be enough left to work the nasal spray.
- Check the nasal spray for damage.

If you think the nozzle may be blocked, **do not use a pin** or anything sharp to clear it.

Try to re-set the nasal spray by following the instructions under ‘Preparing the nasal spray for use’.

If it is still not working, or if it produces anything other than a fine mist (such as a jet of liquid), or if you feel any discomfort using the spray, return it to your pharmacist.

If you use more GENEMIST than you should:

It is important to use GENEMIST as you have been instructed.

If you accidently use more than the recommended number of sprays, talk to your doctor or pharmacist.

If you forget to use GENEMIST:

If you miss a dose, use it when you remember. If it is nearly time for your next dose, wait until then. Do not use a double dose.

If you have any further questions on the use of GENEMIST, ask your doctor or pharmacist.

4. Possible side effects

GENEMIST can have side effects.

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

If any of the following happens, stop using GENEMIST and tell your doctor immediately or go to the casualty department at your nearest hospital:

- difficulty breathing
- swelling of the face, neck, tongue or throat and a skin rash (severe allergic reactions)
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to GENEMIST. 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:

- slowing of growth of children
- 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 include:

- minor nosebleeds – nosebleeds are more likely to occur if you use GENEMIST for more than 6 weeks continuously
- nasal ulceration – which may cause irritation or discomfort in your nose

  You may also get streaks of blood when you blow your nose.
- headache.

Less frequent side effects include:

- pain, burning, irritation, soreness or dryness in the inside of 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 GENEMIST.

5. How to store GENEMIST

Store all medicines out of reach of children.

Store at or below 30 ºC in the container specified.

Do not keep GENEMIST in the fridge or freezer.

Always keep the cap on.

Once opened, you can use GENEMIST up until the last day of the month of the expiry date.

Do not use GENEMIST after the expiry date which is stated on the label or carton.

Medicines should not be disposed of via wastewater or household rubbish. 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 GENEMIST contains:

The active substance is fluticasone furoate. Each 50 µl of nasal spray contains 27,5 µg of fluticasone furoate.

The other ingredients are glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride (preservative), disodium edetate (preservative) and purified water.

What GENEMIST looks like and contents of the pack:

A uniform white suspension.

The nasal spray container consists of an inner container within an outer device. The inner container consists of a Type I or Type III amber glass bottle, closed with a metering spray pump. The outer device is a mostly off-white side-actuated plastic delivery system with a light blue lever and lid containing a stopper. The outer plastic cover has a window for viewing the bottle contents.

GENEMIST is available in three pack sizes:

- 30 sprays with a target net content of 4,5 g
- 60 sprays with a target net content of 6,5 g
- 120 sprays with a target net content of 10 g.

Not all pack sizes may be marketed.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

This leaflet was last revised:

18 March 2021

Registration number:

41/21.5.1/0967

Date of registration:

12 June 2009

PASIËNTINLIGTINGSVOUBILJET

SKEDULERINGSTATUS

S4

GENEMIST 27,5 µg/spuit as neussproei suspensie

Flutikasoonfuroaat

Lees die hele voubiljet aandagtig deur voordat u begin om GENEMIST te gebruik.

- Hou hierdie voubiljet. Dit is moontlik dat u dit weer sal moet lees.
- As u enige verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- GENEMIST is aan u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan moontlik vir hulle skadelik wees, al is hulle simptome dieselfde as u simptome.

Wat in hierdie voubiljet vervat word:

1. Wat GENEMIST is en waarvoor dit gebruik word

GENEMIST bevat die medisyne flutikasoonfuroaat. Dit is ’n steroïed wat help om inflammasie in die neus en irritasie van die oë wat deur allergieë (rinitis) veroorsaak word, te verminder. Die effekte word gewoonlik binne die eerste dag ervaar, alhoewel party mense nie die volle effekte sal ervaar voor etlike dae ná GENEMIST aanvanklik gebruik is nie.
Die dokter het GENEMIST voorgeskryf om te help om simptome wat deur allergieë veroorsaak word, te behandel, insluitend oë wat traan of jeuk, toe- of loopneus, en ’n genies. Simptome kan op spesifieke tye van die jaar voorkom, en kan veroorsaak word deur allergieë vir stuifmeel van gras of bome (hooikoors), of dit kan heeljaar voorkom en veroorsaak word deur allergieë vir diere, stof, huisstof, myte of skimmel. Deur GENEMIST een keer per dag te gebruik, kan u simptome gedurende die dag en nag voorkom. GENEMIST word as ’n fyn missproei in die neus toegedien. GENEMIST is nie vir gebruik in die oë nie. Daar is ’n venstertjie aan die kant van die buitenste plastiekomhulsel van GENEMIST sodat u kan sien hoeveel medisyne in die neussproeibottel oor is. Vra u dokter vir nog medisyne as die hoeveelheid medisyne wat oor is, min word.

2. Wat u moet weet alvorens u GENEMIST gebruik

Moenie in die volgende gevalle GENEMIST gebruik nie:

As u allergies (hipersensitief) vir flutikasoonfuroaat of vir enige van die ander bestanddele in GENEMIST is (dit word in afdeling 6 van hierdie voubiljet uiteengesit).

Waarskuwings en voorsorgmaatreëls:

Sê vir u dokter of gesondheidsorgverskaffer voordat u GENEMIST gebruik as u of u kind:

- Nasale kortikosteroïede kan die normale produksie van hormone in die liggaam affekteer, veral as u vir ’n lang tydperk hoë dosisse gebruik

Neem in die volgende gevalle spesiale sorg met GENEMIST:

- as u dowwe visie of ander visuele versteurings ervaar, moet u met u dokter daaroor praat.

Kinders en adolessente:

Wanneer GENEMIST vir ’n lang tydperk gebruik word, kan dit moontlik daartoe lei dat kinders stadiger groei. Die dokter sal u kind se lengte gereeld meet en seker maak dat u kind die laagste moontlike dosis gebruik.

GENEMIST word nie aanbeveel vir gebruik deur kinders jonger as 2 jaar oud nie.

Ander medisyne en GENEMIST:

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisyne in.)

Sommige medisyne kan moontlik affekteer hoe GENEMIST werk, of dit kan dit waarskynliker maak dat u newe-effekte sal ervaar.

Sê vir u dokter of apteker as u enige van die volgende neem:

- medisyne vir asma
- enige medisyne wat ’n steroïed bevat. Dit kan moontlik sommige ekseemrome, inspuitings, tablette, neussproeie en oog- of oordruppels insluit
- ritonavir (’n medisyne wat gebruik word vir die behandeling van MIV)
- ketokonasool (’n medisyne wat gebruik word om swaminfeksies mee te behandel).

Swangerskap en borsvoeding:

As u swanger is of borsvoed, vermoed dat u moontlik swanger kan wees, of van plan is om swanger te raak, kontak asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u GENEMIST gebruik.

Bestuur van ’n voertuig en gebruik van masjiene:

GENEMIST sal waarskynlik nie u vermoë affekteer om te bestuur en masjiene te gebruik nie.

GENEMIST bevat bensalkoniumchloried:

Bensalkoniumchloried kan moontlik irritasie of swelling binne-in die neus veroorsaak, veral as dit vir ’n lang tydperk gebruik word.

3. Hoe om GENEMIST te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.
Gebruik GENEMIST altyd presies soos u dokter u aangesê het. Maak by u dokter of apteker seker as u nie seker is nie.

Gebruik u GENEMIST een keer per dag op dieselfde tyd van die dag, of so na as moontlik daaraan, om u simptome dwarsdeur die dag en nag te behandel.

GENEMIST word as ’n fyn missproei in die neus gespuit.

Volwassenes en adolessente van 12 jaar oud en ouer:

Die gewone begindosis is 2 spuite in elke neusgat een keer per dag.
Sodra simptome onder beheer is, kan u moontlik u dosis verminder tot 1 spuit in elke neusgat een keer per dag.

Kinders (2 tot 11 jaar oud):

Vir kinders van 2 tot 11 jaar oud is die gewone begindosis 1 spuit in elke neusgat een keer per dag.

As die simptome baie erg is, kan die dokter die dosis moontlik verhoog tot 2 spuite in elke neusgat een keer elke dag totdat die simptome onder beheer is. Daarna kan dit moontlik wees om die dosis te verminder tot 1 spuit in elke neusgat een keer per dag.

As u onder die indruk is dat die effek van GENEMIST te sterk of te swak is, sê vir u dokter of apteker.

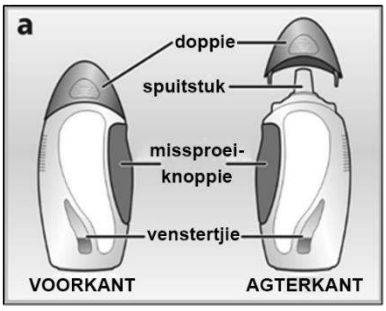
Gebruiksinstruksies:

Hierdie afdeling sluit die volgende inligting in:

- Die neussproei
- Ses belangrike dinge wat u oor GENEMIST moet weet
- Voorbereiding van die neussproei
- Gebruik die neussproei
- Skoonmaak van die neussproei.

Die neussproei:

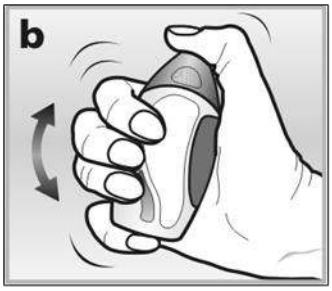
- GENEMIST is verpak in ’n bruin glasbottel met ’n plastiekomhulsel. Dit sal óf 30 óf 60 óf 120 spuite bevat, afhangende van die pakgrootte wat aan u voorgeskryf is (**prentjie a**).
- ’n Venstertjie in die plastiekomhulsel stel u in staat om te sien hoeveel medisyne oor is. U sal die vloeistofvlak vir ’n nuwe spuitbottel met 30 of 60 spuite kan sien (**prentjie a**), maar nie vir ’n nuwe spuitbottel wat 120 spuite lewer nie, omdat die vloeistofvlak bo die venstertjie lê.



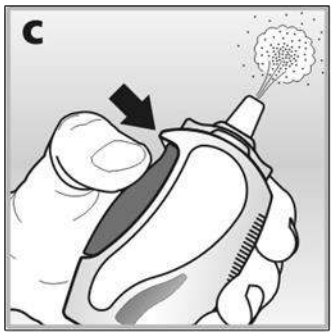
- Die medisyne spuit by die spuitstuk uit wanneer die knoppie aan die kant ferm en heeltemal ingedruk word.
- 'n Verwyderbare doppie beskerm die spuitstuk teen stof en keer dat dit verstop word.

Ses belangrike dinge wat u oor GENEMIST moet weet:

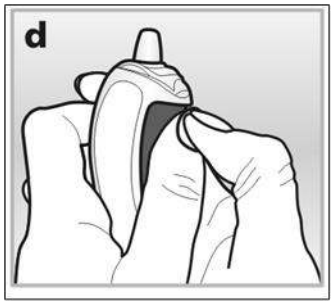
1. Die neussproei word in 'n bruin glasbottel verpak. Om te kyk hoeveel oor is, **hou die neussproei regop teen 'n helder lig**. U sal dan die vlak in die venstertjie kan sien.
2. Wanneer u die neussproei die **eerste keer gebruik,** moet u dit met die doppie op vir sowat 10 sekondes **hard skud**. Dit is belangrik, aangesien GENEMIST baie dik is en vloeibaarder word wanneer u dit deeglik skud (**prentjie b**). Dit sal slegs spuit wanneer dit 'n vloeistof word.



3. Die knoppie aan die kant moet ferm en heeltemal ingedruk word sodat 'n spuit medisyne by die spuitstuk kan uitspuit (**prentjie c**).



4. As u sukkel om die knoppie met u duim in te druk, kan u twee hande gebruik (**prentjie d**).



5. **Hou altyd die doppie op die neussproei** wanneer u dit nie gebruik nie. Die doppie hou stof uit, verseël die drukking, en keer dat die spuitstuk verstop word. Wanneer die doppie op sy plek is, kan die knoppie aan die kant nie per ongeluk ingedruk word nie.
6. **Moet nooit 'n speld** of iets skerp gebruik om die spuitstuk oop te steek nie. Dit sal die neussproei beskadig.

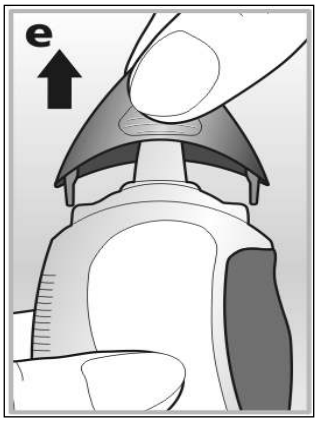
Voorbereiding van die neussproei:

U moet die neussproei voorberei:

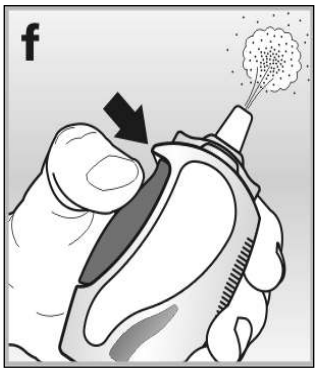
- voordat u dit die eerste keer gebruik
- as u nie die doppie opgesit het nie.

Deur die neussproei voor te berei, help om te verseker dat u altyd die volle dosis medisyne kry. Volg hierdie stappe:

- Met die doppie op sy plek, **skud die neussproei hard** vir sowat 10 sekondes.
- Haal die doppie af deur die kante van die doppie met u duim en wysvinger te druk en dit dan reguit af te trek (**prentjie e**).



- Hou die neussproei regop en wys die spuitstuk weg van u af.
- **Druk die knoppie ferm en heeltemal in. Doen dit minstens 6 keer** om 'n fyn missproei in die lug te spuit (**prentjie f**).

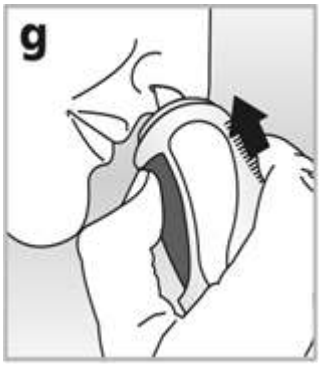


Die neussproei is nou reg vir gebruik.

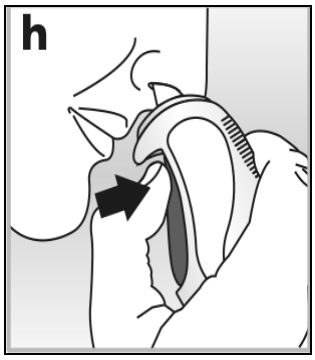
Gebruik die neussproei:

1. **Skud die neussproei hard.**
2. Haal die doppie af.
3. **Blaas u neus** om u neusgat skoon te maak en kantel dan u kop effens vorentoe.

4. Hou die neussproei regop en plaas die spuitstuk versigtig in een van u neusgate (**prentjie g**).



5. Wys die spuitstuk na u neus se buitekant toe, weg van die middelste lyn van u neus af. Dit help om die medisyne by die regte deel van u neus te kry.
6. Asem in deur u neus en **druk die knoppie terselfdertyd ferm en heeltemal in** (**prentjie h**).

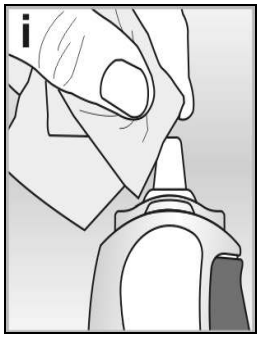


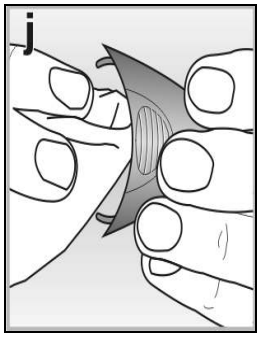
7. Wees versigtig dat die sproei nie in u oë beland nie. As dit gebeur, spoel u oë uit met water.
8. Haal die spuitstuk uit en asem uit deur u mond.
9. As u dokter vir u gesê het om twee spuite per neusgat te gebruik, herhaal stap 4 tot 6 hier bo.
10. Herhaal stap 4 tot 6 vir u ander neusgat.
11. **Sit die doppie** terug op die neussproei.

Skoonmaak van die neussproei:

Ná elke gebruik:

- Vee die spuitstuk en die binnekant van die doppie af (**prentjie i en j**). Moenie water gebruik om dit te doen nie. Vee met ’n skoon, droë snesie.





- **Moet nooit ’n speld** of iets skerp op die spuitstuk gebruik nie.
- **Sit altyd die doppie terug wanneer** u klaar is om stof uit te hou, die drukking te verseël en te keer dat die spuitstuk verstop word.

As die neussproei klaarblyklik nie werk nie:

- Maak seker dat u nog medisyne oor het. Kyk na die vlak deur die venstertjie. As die vlak baie laag is, is daar moontlik nie genoeg oor vir die neussproei om te werk nie.
- Kyk of die neussproei beskadig is.

As u meen die spuitstuk kan moontlik verstop kan wees, **moenie ’n speld** of iets skerp gebruik om dit oop te steek nie.

Probeer om die neussproei te herstel deur die instruksies te volg onder “Voorbereiding van die neussproei vir gebruik”.

As dit steeds nie werk nie, of as dit enigiets anders as ’n fyn missproei (soos byvoorbeeld ’n straal vloeistof) lewer, of as u enige ongemak ervaar met gebruik van die sproei, neem dit terug na u apteker.

As u meer GENEMIST gebruik het as wat u moes:

Dit is belangrik om GENEMIST te gebruik soos u aangesê is.

As u per ongeluk meer as die aanbevole getal spuite gebruik het, praat met u dokter of apteker.

As u vergeet om GENEMIST te gebruik:

As u ’n dosis oorslaan, gebruik dit wanneer u daarvan onthou. As dit amper tyd is vir die volgende dosis, wag tot dan. Moenie ’n dubbeldosis gebruik nie.

As u enige verdere vrae oor die gebruik van GENEMIST het, moet u u dokter of apteker vra.

4. Moontlike newe-effekte

GENEMIST kan newe-effekte veroorsaak.

Nie al die newe-effekte van GENEMIST wat aangemeld is, word by hierdie voubiljet ingesluit nie. As u algemene gesondheid verswak, of as u enige ongunstige effekte ervaar terwyl u GENEMIST gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, hou op om GENEMIST te gebruik en stel u dokter onmiddellik in kennis of gaan na u naaste hospitaal se noodgevalle-afdeling:

- probleme met asemhaling
- swelling van die gesig, nek, tong of keel, en ’n veluitslag (erge allergiese reaksies)
- veluitslag of ’n gejeuk.

Dit is alles baie ernstige newe-effekte. As u hierdie simptome ervaar, het u moontlik 'n ernstige reaksie op GENEMIST gehad. U het moontlik dringende mediese aandag of hospitalisasie nodig.

Sê onmiddellik vir u dokter of gaan onmiddellik na u naaste hospitaal se ongevalle-afdeling as u enige van die volgende opmerk:

- kinders wie se groei verlangsaam
- klein gaatjies (perforasies) in die brug binnekant die neus wat die twee neusgate skei.

Dit is alles ernstige newe-effekte. U kan moontlik dringende mediese aandag nodig hê.

Sê vir u dokter as u enige van die volgende opmerk:

Algemene newe-effekte sluit in:

- geringe neusbloeding – neusbloeding sal meer waarskynlik voorkom wanneer u GENEMIST deurlopend vir langer as 6 weke gebruik
- neus ulserasie – wat moontlik irritasie of ongemak in u neus kan veroorsaak
  U kan moontlik ook strepe bloed sien wanneer u u neus blaas.
- hoofpyn.

Nie-algemene newe-effekte sluit in:

- pyn, brandgevoel, irritasie, pyn of droogheid in die neus.

As u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem word nie, moet u asseblief u dokter of apteker in kennis stel.

Aanmelding van newe-effekte:

Praat met u dokter of apteker as u newe-effekte ervaar. U kan ook newe-effekte by SAHPRA aanmeld deur die "**6.04 Adverse Drug Reaction Reporting Form**" te gebruik wat aanlyn onder SAHPRA-publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van GENEMIST te verskaf.

5. Hoe om GENEMIST te bewaar

Bewaar alle medisyne buite die bereik van kinders.

Bewaar by of benede 30 °C in die gespesifiseerde houer.

Moenie GENEMIST in die yskas of vrieskas sit nie.

Hou altyd die doppie op.

Sodra dit oop is, kan u GENEMIST tot die laaste dag van die vervaldatum se maand gebruik. Moenie GENEMIST ná die vervaldatum op die etiket of boksie gebruik nie.

Medisyne moenie met afvalwater of huishoudelike vullis weggegooi word nie. Vra u apteker hoe om van medisyne ontslae te raak wat nie meer benodig word nie. Hierdie maatreëls sal die omgewing help beskerm.

6. Inhoud van die pakkie en ander inligting

Wat GENEMIST bevat:

Die aktiewe bestanddeel is flutikasoonfuroaat. Elke 50 µl neussproei bevat 27,5 µg flutikasoonfuroaat.

Die ander bestanddele is anhidriese glukose, verspreibare sellulose, polisorbaat 80, bensalkoniumchloried (preserveermiddel), dinatriumedetaat (preserveermiddel) en gesuiwerde water.

Hoe GENEMIST lyk, en wat die inhoud van die pakkie is:

'n Egalige, wit suspensie.

Die neussproeihouer bestaan uit 'n binneste houer binne 'n buitenste apparaat. Die binneste houer bestaan uit 'n Tipe I- of Tipe III-bruinkleurige glasbottel waarop 'n afmetende spuitpomp aangebring is. Die buitenste apparaat is 'n meestal naaswit kant -geaktiveerde plastiekleweringstelsel met 'n ligte blou hefboom en deksel wat 'n prop bevat. Die buitenste plastiekomhulsel het 'n venstertjie om die inhoud van die bottel te kan sien.

GENEMIST is in drie pakgroottes beskikbaar:

- 30 spuite met 'n netto teikeninhoud van 4,5 g
- 60 spuite met 'n netto teikeninhoud van 6,5 g
- 120 spuite met 'n netto teikeninhoud van 10 g.

Nie al die verpakkingsgroottes word noodwendig bemark nie.

Houer van die registrasiesertifikaat:

GlaxoSmithKline South Africa (Edms) Bpk.

Hawkinslaan 39

Epping Industrie 1, 7460

Hierdie voubiljet is laas hersien op:

18 Maart 2021

Registrasienommer:

41/21.5.1/0967

Registrasiedatum:

12 Junie 2009

Handelsmerke is in besit van of gelisensieer aan die GSK-groep van maatskappye.