For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

AVAMYS NASAL SPRAY

1. GENERIC NAME

Fluticasone Furoate Nasal Spray

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains:
Fluticasone Furoate Ph. Eur. 0.05 % w/w
Preservatives: Benzalkonium Chloride Solution IP equivalent to Benzalkonium Chloride 0.015% w/w.
Disodium Edetate IP 0.015% w/w
Each metered dose delivers 27.5 mcg of Fluticasone Furoate Ph. Eur.

List of Excipients

Glucose Anhydrous, Dispersible Cellulose Polysorbate 80, Benzalkonium Chloride Solution, Disodium Edetate and Purified Water.

3. DOSAGE FORM AND STRENGTH

Nasal spray, suspension.

AVAMYS NASAL SPRAY is a white, uniform suspension contained in an amber glass bottle, fitted with a metering (50 microlitres) atomising spray pump. This inner pack is incorporated within a predominantly off-white plastic device with a blue side-actuated lever and a lid which contains a stopper. Each spray of the suspension delivers approximately 27.5 micrograms of micronised fluticasone furoate as an ex-device dose.

4. CLINICAL PARTICULARS

4.1.Therapeutic Indications

For the treatment of symptoms of allergic rhinitis.

4.2.Posology and Method of Administration

AVAMYS NASAL SPRAY is for administration by the intranasal route only. 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 *(see 5.4 Clinical Studies)*.

Populations

For the treatment of seasonal allergic rhinitis and perennial allergic rhinitis:

Adults and Adolescents (12 years and older)

The recommended starting dosage is 2 sprays (27.5 micrograms of fluticasone furoate per spray) in each nostril once daily (total daily dose, 110 micrograms).

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

Children (2 to 11 years)

The recommended starting dosage is 1 spray (27.5 micrograms of fluticasone furoate per spray) in each nostril once daily (total daily dose, 55 micrograms).

Patients not adequately responding to 1 spray in each nostril once daily (total daily dose, 55 micrograms) may use 2 sprays in each nostril once daily (total daily dose, 110 micrograms). Once adequate control of symptoms is achieved, dose reduction to 1 spray in each nostril once daily (total daily dose, 55 micrograms) is recommended.

Children (under 2 years of age)

There are no data to recommend use of *AVAMYS NASAL SPRAY* for the treatment of seasonal or perennial allergic rhinitis in children under 2 years of age.

Elderly

No dosage adjustment required *(see 5.3 Pharmacokinetic Properties)*.

Renal impairment

No dosage adjustment required *(see 5.3 Pharmacokinetic Properties)*.

Hepatic impairment

No dosage adjustment is required in patients with hepatic impairment. *(see 4.4 Special Warnings and Precautions for Use*, and *5.3 Pharmacokinetic Properties).*

4.3.Contraindications

AVAMYS NASAL SPRAY is contraindicated in patients with hypersensitivity to any of the ingredients.

4.4.Special Warnings and Precautions for Use

Based on data with another glucocorticoid metabolised by CYP3A4 co-administration with ritonavir is not recommended because of the potential risk of increased systemic exposure to fluticasone furoate *(see 4.5 Drug Interactions and 5.3 Pharmacokinetic Properties)*.

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. A reduction in growth velocity has been observed in children treated with fluticasone furoate 110 micrograms daily for one year *(see 4.8 Undesirable Effects* and *5.4 Clinical Studies)*. Therefore, children should be maintained on the lowest dose which delivers adequate symptom control *(see 4.2 Posology and Method of Administration)*. As with other intranasal corticosteroids, physicians should be alert to potential systemic steroid effects including ocular changes such as central serous chorioretinopathy *(see 5.4 Clinical Studies)*.

4.5.Drug Interactions

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

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 drugs (*see 4.4 Special Warnings and Precautions for Use, and 5.3 Pharmacokinetic Properties)*.

4.6.Use in Special Populations

Pregnancy and Lactation

Adequate data are not available regarding the use of *AVAMYS NASAL SPRAY* during pregnancy and lactation in humans. *AVAMYS NASAL SPRAY* should be used in pregnancy only if the benefits to the mother outweigh the potential risks to the foetus.

Fertility

There are no data in humans *(see 6 Nonclinical Properties, Reproductive Toxicology)*.

Pregnancy

Following intranasal administration of *AVAMYS NASAL SPRAY* at the maximum recommended human dose (110 micrograms/day), plasma fluticasone furoate concentrations were typically non-quantifiable

and therefore potential for reproductive toxicity is expected to be very low (*see 6 Nonclinical Properties, Reproductive Toxicology*).

Lactation

The excretion of fluticasone furoate into human breast milk has not been investigated.

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 *AVAMYS NASAL SPRAY*.

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

Clinical Trial Data

Respiratory, thoracic and mediastinal disorders

Very common:	Epistaxis
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 *AVAMYS NASAL SPRAY* and placebo.	
Common:	Nasal ulceration

Children

Musculoskeletal and connective tissue disorders

Not known:	Growth retardation
In a one-year clinical study assessing growth in pre-pubescent children receiving 110 micrograms of fluticasone furoate once daily, an average treatment difference of -0.27 cm per year in growth velocity was observed compared to placebo *(see 5.4 Clinical Studies)*.	

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

4.9.Overdose

Symptoms and Signs

In a bioavailability study, intranasal doses of up to 24 times the recommended daily adult dose were studied over three days with no adverse systemic effects observed *(see 5.3 Pharmacokinetic Properties)*.

Treatment

Acute overdose is unlikely to require any therapy other than observation.

5. PHARMACOLOGICAL PROPERTIES

5.1.Mechanism of Action

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

5.2.Pharmacodynamic Properties

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

5.3.Pharmacokinetic Properties

Absorption

Fluticasone furoate undergoes extensive first-pass metabolism and incomplete absorption in the liver and gut resulting in negligible systemic exposure. The intranasal dosing of 110 micrograms once daily does not typically result in measurable plasma concentrations (<10 picograms/mL). The absolute bioavailability for intranasal fluticasone furoate administered as 880 micrograms three times per day (2640 micrograms 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 17 beta-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 17 beta-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.

Special Patient Populations

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 to the younger subjects.

Children

Fluticasone furoate is typically not quantifiable (< 10 pg/mL) following intranasal dosing of 110 micrograms once daily. Quantifiable levels were observed in < 16% of paediatric patients following intranasal dosing of 110 micrograms once daily and only < 7% of paediatric patients following 55 micrograms 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).

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 microgram dose of orally inhaled fluticasone furoate in patients with moderate hepatic impairment (Child-Pugh B) resulted in increased C_{max} (42%) and AUC (0-∞) (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 micrograms) 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 micrograms). Based on these findings the average predicted exposure for 110 micrograms of intranasal fluticasone furoate in this patient population would not be expected to result in suppression of cortisol.

Other pharmacokinetic

Fluticasone furoate is typically not quantifiable (<10 pg/mL) following intranasal dosing of 110 micrograms once daily. Quantifiable levels were only observed in <31% of patients aged 12 years and above and in <16% of paediatric patients following intranasal dosing of 110 micrograms once daily. There was no evidence for gender, age (including paediatrics), or race to be related to those subjects with quantifiable levels, when compared to those without.

5.4.Clinical Studies

Adult and Adolescent Seasonal Allergic Rhinitis

Once daily 110 micrograms *AVAMYS NASAL SPRAY* resulted in a significant improvement in daily reflective (how patient felt over the preceding 12 hours) and instantaneous (how patient felt at the time of assessment) pre-dose total nasal symptom scores (rTNSS and iTNSS, comprising rhinorrhea, nasal congestion, sneezing and nasal itching) and daily reflective and instantaneous total ocular symptom scores (rTOSS, comprising itching/burning, tearing/watering and redness of the eyes) versus placebo (see table below). The improvement in nasal and ocular symptoms was maintained over the full 24 hours after once daily administration.

Seasonal Allergic Rhinitis: Primary and secondary key endpoints				
Study	**Primary Endpoint: Daily rTNSS**		**Secondary Endpoint: Daily rTOSS**	
	LS Mean Difference	**P-value (95% CI)**	**LS Mean Difference**	**P-value (95% CI)**
FFR20001	-2.012	<0.001 (-2.58, -1.44)	-	-
FFR30003	-0.777	0.003 (-1.28, -0.27)	-0.546	0.008 (-0.95, -0.14)
FFR103184	-1.757	<0.001 (-2.28, -1.23)	-0.741	<0.001 (-1.14, -0.34)
FFR104861	-1.473	<0.001 (-2.01, -0.94)	-0.600	0.004 (-1.01, -0.19)
rTNSS = reflective total nasal symptom scores; rTOSS = reflective total ocular symptom scores; LS = Least square; LS Mean Difference = LS mean change from baseline in active – LS mean change from baseline in placebo; CI = Confidence interval				

The distribution of the patients' perception of overall response to therapy (using a 7-point scale ranging from significantly improved to significantly worse) favoured fluticasone furoate 110 micrograms over placebo, with a statistically significant treatment difference. Onset of action was experienced as early as eight hours after initial administration in two studies. Significant improvement in symptoms was observed in the first 24 hours in all four studies and continued to improve over several days. The patients' quality of life (as assessed by the Rhinoconjunctivitis Quality of Life Questionnaire – RQLQ), was significantly improved from baseline with *AVAMYS NASAL SPRAY* compared to placebo. (Minimum Important Difference in all studies = improvement of at least -0.5 over placebo; treatment difference -0.690, p<0.001, 95% CI -0.84, -0.54).

Adult and Adolescent Perennial Allergic Rhinitis

Intranasal fluticasone furoate 110 micrograms once daily resulted in a significant improvement in daily rTNSS (LS mean difference = -0.706, P=0.005, 95% CI -1.20, -0.21). The improvement in nasal symptoms was maintained over the full 24 hours after once daily administration. The distribution of patients' perception of overall response to therapy was also significantly improved compared to placebo.

In a two-year study designed to assess the ocular safety of fluticasone furoate (110 micrograms once daily intranasal spray), adults and adolescents with perennial allergic rhinitis received either fluticasone furoate (n=367) or placebo (n=181). The primary outcomes [time to increase in posterior subcapsular opacity (≥0.3 from baseline in Lens Opacities Classification System, Version III (LOCS III grade)) and time to increase in intraocular pressure (IOP; ≥7 mmHg from baseline)] were not statistically significant between the two groups. Increases in posterior subscapsular opacity (≥0.3 from baseline) were more frequent in subjects treated with fluticasone furoate 110 micrograms [14 (4%)] versus placebo [4 (2%)] and were transient in nature for ten subjects in the fluticasone furoate group and two subjects in the placebo group. Increases in IOP (≥7 mmHg from baseline) were more frequent in subjects treated with fluticasone furoate 110 micrograms: 7 (2%) for fluticasone furoate 110 micrograms once daily and 1 (<1%) for placebo. These events were transient in nature for six subjects in the fluticasone furoate group and one placebo subject. At weeks 52 and 104, 95% of subjects in both treatment groups had posterior subcapsular opacity values within ± 0.1 of baseline values for each eye and, at week 104, ≤1% of subjects in both treatment groups had ≥0.3 increase from baseline in posterior subcapsular opacity. At weeks 52

and 104, the majority of subjects (>95%) had IOP values of within ± 5mmHg of the baseline value. Increases in posterior subcapsular opacity or IOP were not accompanied by any adverse events of cataracts or glaucoma.

Children

The paediatric posology is based on assessment of the efficacy data across the allergic rhinitis population in children. In a seasonal allergic rhinitis study in children, *AVAMYS NASAL SPRAY* 110 micrograms over two weeks was effective on primary (daily rTNSS LS mean difference = -0.616, P=0.025, 95% CI -1.15, -0.08) and all secondary nasal endpoints, except the individual reflective score for rhinorrhea. No significant differences were observed between 55 micrograms *AVAMYS NASAL SPRAY* and placebo on any endpoint.

In a perennial allergic rhinitis study, *AVAMYS NASAL SPRAY* 55 micrograms was effective on daily rTNSS (LS mean difference = -0.754, P=0.003, 95% CI -1.24, -0.27). Although there was a trend towards improvement in rTNSS in 100 micrograms, this did not reach statistical significance (LS mean difference = -0.452, P=0.073, 95% CI -1.24, -0.04). Post-hoc analysis of efficacy data over 6 and 12 weeks from this study, and a 6-week HPA-axis safety study, each showed that the improvement in rTNSS for fluticasone furoate 110 micrograms nasal spray over placebo was statistically significant.

A randomised, double-blind, parallel-group, multicenter, one-year placebo-controlled clinical growth study evaluated the effect of fluticasone furoate nasal spray 110 micrograms daily on growth velocity in 474 prepubescent children (5 to 7.5 years of age for girls and 5 to 8.5 years of age for boys) with stadiometry. Mean growth velocity over the 52-week treatment period was lower in the patients receiving fluticasone furoate (5.19 cm/year) compared to placebo (5.46 cm/year). The mean treatment difference was -0.27 cm per year [95% CI -0.48 to -0.06].

6. NONCLINICAL PARTICULARS

6.1. Animal Toxicology or Pharmacology

Findings in general toxicology studies were similar to those observed with other glucocorticoids and are not considered to be clinically relevant to intranasal use of *AVAMYS NASAL SPRAY*.

Carcinogenesis, mutagenesis

There were no treatment-related increases in the incidence of tumours in two-year inhalation studies in rats and mice.

AVAMYS NASAL SPRAY was not genotoxic *in vitro* or *in vivo*.

Reproductive toxicology

The potential for reproductive toxicity was assessed in animals by inhalation administration to ensure high systemic exposure to fluticasone furoate. There were no effects on mating performance or fertility of male or female rats. In rats, developmental toxicity was confined to an increased incidence of incompletely ossified sternabrae in association with lower foetal weight. High doses in rabbits induced

abortion. These findings are typical following systemic exposure to potent corticosteroids. There were no major skeletal or visceral abnormalities in either rats or rabbits, and no effect on pre- or post-natal development in rats.

7. DESCRIPTION

AVAMYS NASAL SPRAY is a white, uniform suspension contained in an amber glass bottle, fitted with a metering (50 µL) atomising spray pump. This bottle is incorporated within a predominantly off white plastic device with a dose indicator window, a light blue side-actuated lever and a lid which contains a stopper. Each spray of the suspension delivers approximately 27.5 micrograms of micronised Fluticasone Furoate as an ex-device dose.

8. PHARMACEUTICAL PARTICULARS

8.1.Incompatibilities

None

8.2.Shelf Life

36 months

The expiry date is indicated on the label and packaging.

8.3.Packaging Information

Nature and Contents of Container

AVAMYS NASAL SPRAY is a drug suspension contained within a glass bottle fitted with a metering spray pump, which is encased in an off-white plastic device with a blue side-actuated lever and lid.

The fill weight of the products are sufficient to deliver a minimum of 60 or 120 sprays after priming.

8.4.Storage and Handling Information

Store in a dry place at a temperature not exceeding 30°C.
Do not refrigerate or freeze.
Keep out of reach of children

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 *AVAMYS NASAL SPRAY* 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

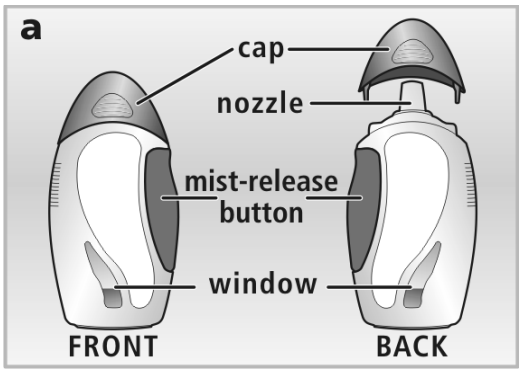
spray vigorously each time before use. The cap must be replaced after use to keep the nozzle clean and to prevent the need for re-priming.

This section includes the following information:

- **The nasal spray**
- **Six important things you need to know about *AVAMYS NASAL SPRAY***
- **Preparing the nasal spray**
- **Using the nasal spray**
- **Cleaning the nasal spray**

The nasal spray

- Your medicine comes in a brown glass bottle inside a plastic casing. It will contain either 60 or 120 sprays, depending on the pack size that has been prescribed for you **(picture a)**.



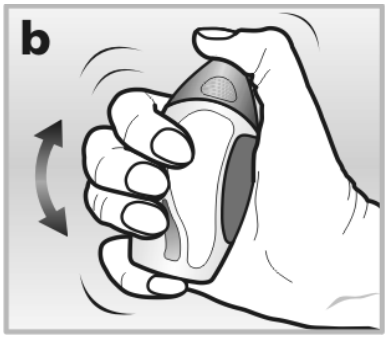
- A window in the plastic casing allows you to see how much medicine is left. You will be able to see the liquid level for a new 60 spray bottle (**picture a)**, but not for a new 120 spray bottle because the liquid level is above the window.

- The medicine sprays out of the nozzle when the button on the side is **pressed firmly all the way in**.

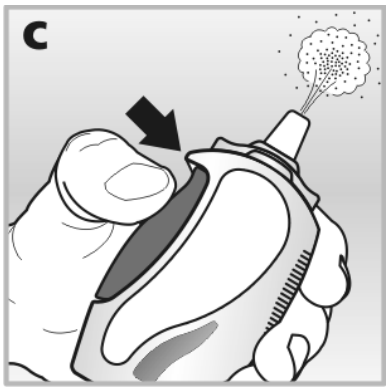
- A removable cap protects the nozzle from dust and prevents it from blocking up.

Six important things you need to know about *AVAMYS NASAL SPRAY*

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.

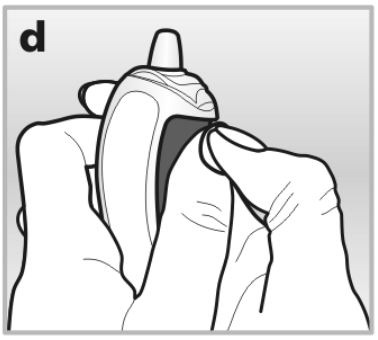


2. When you **first use the nasal spray you must shake it vigorously** with the cap on for about 10 seconds. This is important as *AVAMYS NASAL SPRAY* is very thick and becomes more liquid when you shake it well **(picture b)**. It will only spray when it becomes liquid.



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)**.



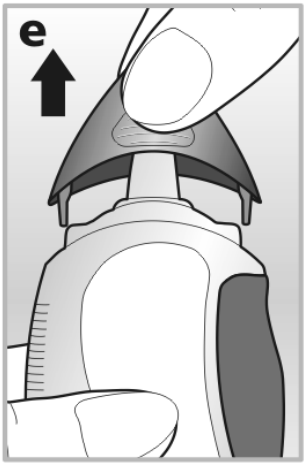
5. **Always keep the cap on the nasal spray** when you are not using it. The cap keeps the dust out, seals in the pressure and stops the nozzle from blocking up. When the cap is in place the button on the side can't be pressed accidentally.

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.

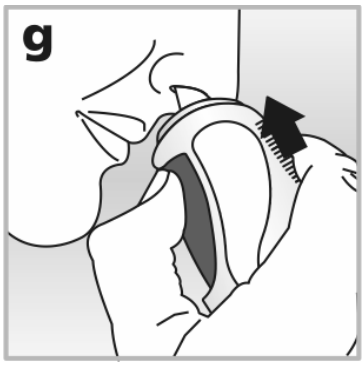


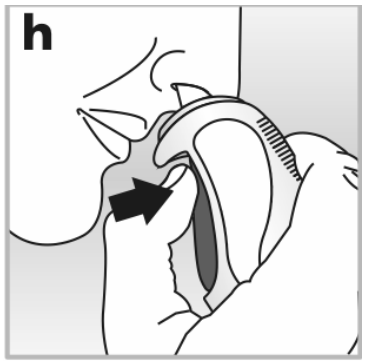
Preparing the nasal spray helps to make sure you always get the full dose of medicine. Follow these steps:

- 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 nozzole out and breathe out through your mouth.
9. If your doctor has told you to take 2 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.

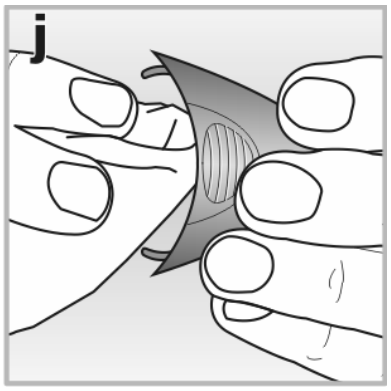




Cleaning the nasal spray

After each use:

- Wipe the nozzle and the inside of the cap **(picture i and j)**. Don't 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, **don't use a pin** or anything sharp to clear it.
- Try to reset it 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.

9. PATIENT COUNSELLING INFORMATION

Registered Medical Practitioners may counsel their patients (and/or their patient's caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contraindications of *AVAMYS NASAL SPRAY*. Patients (and/or their patient's caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

10. DETAILS OF MANUFACTURER

Manufactured by:
Glaxo Wellcome S.A,
Avenida de Extremadura 3,
09400 Aranda De Duero,
Burgos, Spain

For further information please contact:
GlaxoSmithKline Pharmaceuticals Limited
Registered Office:
Dr. Annie Besant Road, Worli,
Mumbai 400 030 India.

11. DETAILS OF PERMISSION OR LICENSE NUMBER WITH DATE

Import-279/2011 dated 9 August 2011

12. DATE OF REVISION

02 December 2025

Version AVM/PI/IN/ARD/2025/01

Adapted from GDS 11 / IPI 10 Fluticasone furoate (Intranasal formulation) dated 03 April 2018