ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE MEDICINAL PRODUCT

FLUTICASONE FURATE GSK 27.5 micrograms/spray
nasal spray suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each spray actuation delivers 27.5 micrograms of fluticasone furoate.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, suspension.

White suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Adults, adolescents (12 years and over) and children (6 – 11 years)

Fluticasone furoate GSK is indicated for the treatment of:
• the symptoms of allergic rhinitis

4.2 Posology and method of administration

Fluticasone furoate 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. However, it may take several days of treatment to achieve maximum benefit, and the patient should be informed that their symptoms will improve with continuous regular use (see section 5.1). The duration of treatment should be restricted to the period that corresponds to allergenic exposure.

Adults and Adolescents (12 years and over)
The recommended starting dose is two spray actuations (27.5 micrograms of fluticasone furoate per spray actuation) in each nostril once daily (total daily dose, 110 micrograms).

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

Children (6 to 11 years of age)
The recommended starting dose is one spray actuation (27.5 micrograms of fluticasone furoate per spray actuation) in each nostril once daily (total daily dose, 55 micrograms).

Patients not adequately responding to one spray actuation in each nostril once daily (total daily dose, 55 micrograms) may use two spray actuations in each nostril once daily (total daily dose, 110 micrograms). Once adequate control of symptoms is achieved, dose reduction to one spray actuation in each nostril once daily (total daily dose, 55 micrograms) is recommended.
Children under 6 years of age: The experience in children under the age of 6 years is limited (see section 5.1 and 5.2). Safety and efficacy in this group has not been well established.

Elderly Patients: No dose adjustment is required in this population (see section 5.2).

Renal Impaired Patients: No dose adjustment is required in this population (see section 5.2).

Hepatic Impaired Patients: No dose adjustment is required in mild to moderate hepatic impairment. There are no data in patients with severe hepatic impairment (see section 4.4 and 5.2).

The intranasal device should be shaken before use. The device is primed by pressing the mist release button for at least six spray actuations (until a fine mist is seen), whilst holding the device upright. Re-priming (approximately 6 sprays until a fine mist is seen) is only necessary if the cap is left off for 5 days or the intranasal device has not been used for 30 days or more. The device should be cleaned after each use and the cap replaced.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients of Fluticasone furoate GSK.

4.4 Special warnings and precautions for use

Fluticasone furoate undergoes extensive first-pass metabolism, therefore the systemic exposure of intranasal fluticasone furoate in patients with severe liver disease is likely to be increased. This may result in a higher frequency of systemic adverse events (see section 4.2 and 5.2). Caution is advised when treating these patients.

Ritonavir
Concomitant administration with ritonavir is not recommended because of the risk of increased systemic exposure of fluticasone furoate (see section 4.5).

Systemic effects of nasal corticosteroid may occur, particularly at high doses prescribed for prolonged periods. These effects vary between patients and different corticosteroids (see section 5.2).

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 110 micrograms once daily was not associated with hypothalamic-pituitary-adrenal (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 is maintained. As with all intranasal corticosteroids, the total systemic burden of corticosteroids should be considered whenever other forms of corticosteroid treatment are prescribed concurrently.

Growth retardation has been reported in children receiving some nasal corticosteroids at licensed doses. 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 (see section 5.1).

If there is any reason to believe that adrenal function is impaired, care must be taken when transferring patients from systemic steroid treatment to fluticasone furoate.

Fluticasone furoate GSK contains benzalkonium chloride. It may cause irritation of the nasal mucosa.
4.5 Interaction with other medicinal products and other forms of interaction

Fluticasone furoate is rapidly cleared by extensive first pass metabolism mediated by the cytochrome P450 3A4.

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

Caution is recommended when co-administering fluticasone furoate with potent CYP3A4 inhibitors as an increase in systemic exposure cannot be ruled out. In a drug 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 a statistically significant difference in 24 hour serum cortisol levels between the two groups (see section 4.4).

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.

4.6 Pregnancy and lactation

There are no adequate data from the use of fluticasone furoate in pregnant women. In animal studies glucocorticoids have been shown to induce malformations including cleft palate and intra-uterine growth retardation. This is not likely to be relevant for humans given recommended nasal doses which results in minimal systemic exposure (see section 5.2). Fluticasone furoate should be used in pregnancy only if the benefits to the mother outweigh the potential risks to the foetus or child.

It is unknown whether nasal administered fluticasone furoate is excreted in human breast milk. Administration of fluticasone furoate to women who are breastfeeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed as fluticasone furoate is not expected to affect this ability.

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 frequencies: Very common ≥1/10; Common ≥1/100 to <1/10; Uncommon ≥1/1000 to <1/100; Rare ≥1/10,000 to <1/1000; Very rare <1/10,000.

<table>
<thead>
<tr>
<th>Respiratory, thoracic and mediastinal disorders</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common</td>
<td>Epistaxis</td>
</tr>
<tr>
<td>Common</td>
<td>Nasal ulceration</td>
</tr>
</tbody>
</table>

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.
4.9 Overdose

In a bioavailability study, intranasal doses of up to 2640 micrograms per day were administered over three days with no adverse systemic effects observed (see section 5.2). Acute overdose is unlikely to require any therapy other than observation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids. ATC code: R01AD12

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

Clinical experience:
Seasonal Allergic Rhinitis in adults and adolescents
Compared with placebo, fluticasone furoate nasal spray 110 micrograms once daily significantly improved nasal symptoms (comprising rhinorrhoea, nasal congestion, sneezing and nasal itching) and ocular symptoms (comprising itching/burning, tearing/watering and redness of the eyes) in all 4 studies. Efficacy was maintained over the full 24-hours dosing period with once daily administration.

Onset of therapeutic benefit was observed as early as 8 hours after initial administration, with further improvement observed for several days afterwards. Fluticasone furoate nasal spray significantly improved the patients’ perception of overall response to therapy, and the patients’ disease-related quality of life (Rhinoconjunctivitis Quality of Life Questionnaire – RQLQ), in all 4 studies.

Perennial Allergic Rhinitis in adults and adolescents:
Fluticasone furoate nasal spray 110 micrograms once daily significantly improved nasal symptoms as well as patients’ perception of overall response to therapy compared to placebo in both studies. Fluticasone furoate nasal spray 110 micrograms once daily significantly improved ocular symptoms as well as improving patients’ disease-related quality of life (RQLQ) compared to placebo in one study. Efficacy was maintained over the full 24-hour dosing period with once daily administration.

Seasonal and perennial allergic rhinitis in children:
The paediatric posology is based on assessment of the efficacy data across the allergic rhinitis population in children.
In seasonal allergic rhinitis, fluticasone furoate nasal spray 110 micrograms once daily was effective but no significant differences were observed between fluticasone furoate nasal spray 55 micrograms once daily and placebo on any endpoint.
In perennial allergic rhinitis, fluticasone furoate nasal spray 55 micrograms once daily exhibited a more consistent efficacy profile than fluticasone furoate nasal spray 110 micrograms once daily over 4 weeks’ treatment. Post-hoc analysis over 6 and 12 weeks in the same study, as well as 6-week HPA axis safety study, supported the efficacy of fluticasone furoate nasal spray 110 micrograms once daily. A 6-week study that assessed the effect of fluticasone furoate nasal spray 110 micrograms once daily on adrenal function in children aged 2 to 11 years showed that there was no significant effect on 24-hour serum cortisol profiles, compared with placebo.
Results from a placebo-controlled knemometry study of fluticasone furoate nasal spray 110 micrograms once daily revealed no clinically relevant effects on short-term lower leg growth rate in children (6 to 11 years).

Seasonal and perennial allergic rhinitis in children (under 6 years):
Safety and efficacy studies were performed in a total of 271 patients from 2 to 5 years of age in both seasonal and perennial allergic rhinitis, of whom 176 were exposed to fluticasone furoate.
Safety and efficacy in this group has not been well established.

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 micrograms once daily does not typically result in measurable plasma concentrations (<10 pg/ml). The absolute bioavailability for intranasal fluticasone furoate is 0.50 %, such that less than 1 microgram of fluticasone furoate would be systemically available after administration of 110 micrograms (see section 4.9).

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:
In the majority of patients fluticasone furoate is not quantifiable (< 10 pg/ml) following intranasal dosing of 110 micrograms once daily. Quantifiable levels were observed in 15.1 % of paediatric patients following intranasal dosing of 110 micrograms once daily and only 6.8 % of paediatric patients following 55 micrograms once daily. There was no evidence for higher quantifiable levels of fluticasone furoate in younger children (less than 6 years of age). Median fluticasone furoate concentrations in those subjects with quantifiable levels at 55 micrograms were 18.4 pg/ml and 18.9 pg/ml for 2-5 yrs and 6-11 yrs, respectively. At 110 micrograms, median concentrations in those subjects with quantifiable levels were 14.3 pg/ml and 14.4 pg/ml for 2-5 yrs and 6-11 yrs, respectively. The values are similar to those seen in adults (12+) where median concentrations in those subjects with quantifiable levels were 15.4 pg/ml and 21.8 pg/ml at 55 micrograms and 110 micrograms, respectively.

Elderly:
Only a small number of elderly patients (≥ 65 years, n=23/872; 2.6 %) provided pharmacokinetic data. There was no evidence for a higher incidence of patients with quantifiable fluticasone furoate concentrations in the elderly, when compared with the younger patients.

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 with intranasal fluticasone furoate in patients with hepatic impairment. A study of a single 400 microgram dose of orally inhaled fluticasone furoate in patients with moderate hepatic impairment resulted in increased Cmax (42 %) and AUC(0-∞) (172 %) and a modest (on average 23 %) decrease in cortisol levels in patients compared to healthy subjects. From this study the average predicted exposure of 110 micrograms of intranasal fluticasone furoate in patients with moderate hepatic impairment would not be expected to result in suppression of cortisol. Therefore moderate
hepatic impairment is not predicted to result in a clinically relevant effect for the normal adult dose. There are no data in patients with severe hepatic impairment. The exposure of fluticasone furoate is likely to be further increased in such patients.

5.3 Preclinical safety data

Findings in general toxicology studies were similar to those observed with other glucocorticoids and are associated with exaggerated pharmacological activity. These findings are not likely to be relevant for humans given recommended nasal doses which results in minimal systemic exposure. No genotoxic effects of fluticasone furoate have been observed in conventional genotoxicity tests. Further, there were no treatment-related increases in the incidence of tumours in two year inhalation studies in rats and mice.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glucose anhydrous
Dispersible cellulose
Polysorbate 80
Benzalkonium chloride
Disodium edetate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
In-use shelf life: 2 months

6.4 Special precautions for storage

Do not refrigerate or freeze.

6.5 Nature and contents of container

Fluticasone furoate GSK nasal spray is a predominantly off-white plastic device with a dose indicator window, light blue side actuated lever and lid which contains a stopper. The plastic device contains the nasal spray suspension within a Type I amber bottle (glass) fitted with a metering spray pump.

The medicinal product is available in three pack sizes: 30, 60 and 120 sprays.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Glaxo Group Ltd
Greenford, Middlesex, UB6 0NN
8. **MARKETING AUTHORISATION NUMBER(S)**

EU/1/08/474/001  
EU/1/08/474/002  
EU/1/08/474/003

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

06/10/2008

10. **DATE OF REVISION OF THE TEXT**

{MM/YYYY}

Detailed information on this medicine is available on the European Medicines Agency (EMEA) website:  
http://www.emea.europa.eu/
ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORIZATION
A. MANUFACTURING AUTHORITY RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Glaxo Operations UK, Ltd,(trading as Glaxo Wellcome Operations)
Harmire Road
Barnard Castle
County Durham
DL12 8DT

B. CONDITIONS OF THE MARKETING AUTHORIZATION

- CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORIZATION HOLDER

Medicinal product subject to medical prescription.

- CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

Not applicable.

- OTHER CONDITIONS

Pharmacovigilance system

The MAH must ensure that the system of pharmacovigilance, as described in version 6.2 (YM2008/00227/00) presented in Module 1.8.1. of the Marketing Authorisation Application, is in place and functioning before and whilst the product is on the market.

Risk Management plan

The MAH commits to performing the studies and additional pharmacovigilance activities detailed in the Pharmacovigilance Plan, as agreed in version GM2006/00247/04 of the Risk Management Plan (RMP) presented in Module 1.8.2. of the Marketing Authorisation Application and any subsequent updates of the RMP agreed by the CHMP.

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, the updated RMP should be submitted at the same time as the next Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted
- When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities
- Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached
- At the request of the EMEA
ANNEX III

LABELLING AND PACKAGE LEAFLET
A. LABELLING
1. **NAME OF THE MEDICINAL PRODUCT**

Fluticasone furoate GSK 27.5 micrograms/spray nasal spray suspension
Fluticasone furoate

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

Each spray delivers 27.5 micrograms of fluticasone furoate

3. **LIST OF EXCIPIENTS**

Also contains: Glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride, disodium edetate, purified water

4. **PHARMACEUTICAL FORM AND CONTENTS**

Nasal spray, suspension
1 bottle - 30 sprays
1 bottle - 60 sprays
1 bottle - 120 sprays

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**

Shake well before use
Read the package leaflet before use.
Nasal use

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

8. **EXPIRY DATE**

*EXP {MM/YYYY}*
In-use shelf life: 2 months
9. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Glaxo Group Ltd
Greenford, Middlesex, UB6 0NN
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/08/474/001
EU/1/08/474/002
EU/1/08/474/003

13. BATCH NUMBER

LOT {Number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Fluticasone furoate GSK
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

INTRANASAL SPRAY/DEVICE LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION
Fluticasone furoate GSK 27.5 micrograms/spray nasal spray suspension
Fluticasone furoate

2. METHOD OF ADMINISTRATION
Read the package leaflet before use

3. EXPIRY DATE
EXP {MM/YYYY]

4. BATCH NUMBER
LOT {Number}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT
30 sprays
60 sprays
120 sprays

6. OTHER
B. PACKAGE LEAFLET
Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Never pass it on to others. It may harm them, even if their symptoms seem the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

In this leaflet:
1. What Fluticasone furoate GSK is and what it is used for
2. Before you use Fluticasone furoate GSK
3. How to use Fluticasone furoate GSK
4. Possible side effects
5. How to store Fluticasone furoate GSK
6. Further information

1. WHAT FLUTICASONE FUROATE GSK IS AND WHAT IT IS USED FOR
Fluticasone furoate GSK nasal spray is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing and watery, itchy or red eyes, in adults and children aged 6 years and over.
Allergy symptoms can occur at specific times of the year and be caused by allergy to pollen from grass or trees (hayfever), or they can occur all year around and be caused by allergy to animals, house-dust mites or moulds.
Fluticasone furoate GSK belongs to a group of medicines called glucocorticoids.
Fluticasone furoate GSK works to decrease inflammation caused by allergy (rhinitis).

2. BEFORE YOU USE FLUTICASONE FUROATE GSK
Do not use Fluticasone furoate GSK:
If you are allergic (hypersensitive) to fluticasone furoate or any of the other ingredients of Fluticasone furoate GSK.

Take special care with Fluticasone furoate GSK:
If you have any liver problems, tell your doctor or pharmacist. Your doctor may adjust your dose of Fluticasone furoate GSK.
Taking nasal glucocorticoids (such as Fluticasone furoate GSK) for a long time may cause children to grow more slowly. The doctor will check your child’s height regularly, and make sure he or she is taking the lowest possible effective dose.

Taking other medicines
Tell your doctor if you are taking, or have recently taken, any other medicines, including those bought without a prescription.
It is especially important to tell your doctor if you are taking, or have recently taken any of the following medicines:
- steroid tablets or injected steroids
- steroid creams
- medicines for asthma
- ritonavir, used to treat HIV
• ketoconazole, used to treat fungal infections

Your doctor will assess whether you should take Fluticasone furoate GSK with these medicines.

**Pregnancy and breast-feeding**
Do not use Fluticasone furoate GSK if you are pregnant, or planning to become pregnant, unless your doctor or pharmacist tells you to.
Do not use Fluticasone furoate GSK if you are breast feeding unless your doctor or pharmacist tells you to.

**Driving and using machines**
Fluticasone furoate GSK is unlikely to affect your ability to drive and use machines.

**Important information about some of the ingredients of Fluticasone furoate GSK**
Fluticasone furoate GSK contains benzalkonium chloride. In some patients this can cause irritation in the inside of the nose. Tell your doctor or pharmacist if you feel discomfort when using the spray.

3. **HOW TO USE FLUTICASONE FUROATE GSK**

Always use Fluticasone furoate GSK exactly as your doctor has told you. You should check with your doctor if you are not sure.

**When to use it and how much to use**
Fluticasone furoate GSK is sprayed into the nose as a fine mist. It has virtually no taste. Fluticasone furoate GSK is not for use in the eyes.

**When to use Fluticasone furoate GSK**
- Use once a day
- Use at the same time each day.
  This will treat your symptoms throughout the day and night.

**How long Fluticasone furoate GSK takes to work**
Some people will not feel the full effects until several days after first using Fluticasone furoate GSK. However, it is usually effective within 8 to 24 hours of use.

**Adults and children 12 years and over**
- 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 under 12 years**
- In children aged 6 to 11 the usual starting dose is 1 spray in each nostril once every day.
- If symptoms are very bad your doctor may increase the dose to 2 sprays in each nostril once every day until the symptoms are under control. It may then be possible for the dose to be reduced to 1 spray in each nostril once every day.
- Do not use in children under 6 years old.

**If you use more Fluticasone furoate GSK than you should**
Talk to your doctor or pharmacist.

**If you forget to use Fluticasone furoate GSK**
- If you miss a dose, take it when you remember.
- If it is nearly the time for your next dose, wait until then. Do not take a double dose to make up for a forgotten dose.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

**How to test the nasal spray before use**

**The nasal spray**
- Your medicine comes in a glass bottle inside a plastic casing.
- The glass bottle contains either 30, 60 or 120 sprays.
- A window on the side of the casing allows you to see how much medicine is left. A bottle containing 30 sprays will not appear full when you first receive it.
- The medicine sprays out of the nozzle when the button on the side is firmly pressed.
- The nozzle is protected by a removable cap.

![Diagram of nasal spray components](image)

**Testing the nasal spray**

![Testing steps](image)

The first time you use the nasal spray, you must test that it is working properly. If you have left the cap off or have not used your spray for nearly a month, follow steps 1-4 below.

1. With the cap on, shake the nasal spray.
2. Remove the cap by gently squeezing the sides of the cap with your thumb and forefinger and pull it straight off – see picture a.
3. Holding the nasal spray upright, point the nozzle away from you and firmly press the button on the side at least 6 times to release a fine spray into the air – see picture b.
4. The nasal spray is now ready for use.

If you drop the spray, check for damage and test it again (steps 1-4 above). If the spray is damaged, 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.
Using your nasal spray

Blow your nose to clear your nostrils. Shake the spray gently before each use.

1. Tilt your head forward a little bit.
2. Hold the nasal spray upright and carefully place the nozzle in one of your nostrils – see picture c.
3. Point the end of the nozzle toward the outside of your nose, away from the centre ridge of your nose. This helps to get the medicine to the right part of your nose.
4. As you breathe in through your nose, firmly press the button once to spray the medicine into your nose – see picture d.

Be careful not to get any spray into your eyes. If you do, rinse your eyes with water.
5. Take the nozzle out and breathe out through your mouth.
6. Repeat steps 1 to 5 for your other nostril.
7. If your doctor has told you to use 2 sprays per nostril, repeat all the 6 steps above.

Cleaning your nasal spray

1. After each use, wipe the nozzle and the inside of the cap – see pictures e and f.

Don’t use water to do this, wipe with a clean, dry tissue.

If the spray becomes blocked, do not try and unblock the nozzle with a pin or sharp object as this will damage the spray mechanism:

Return it to your pharmacist.

2. Always replace the cap once you have finished to keep out dust.

If you use more Fluticasone furoate GSK than you should
Talk to your doctor or pharmacist.

If you forget to use Fluticasone furoate GSK
• If you miss a dose take it when you remember.
• If it is nearly the time for your next dose, wait until then. Do not take a double dose to make up for a forgotten dose.
4. POSSIBLE SIDE EFFECTS

Like all medicines, Fluticasone furoate GSK can cause side effects, although not everybody gets them. Possible side effects are listed below:

**Very common side effects** (These can affect more than 1 person in 10)
- Nosebleeds (generally minor), particularly if you use Fluticasone furoate GSK for more than 6 weeks continuously.

**Common side effects** (These can affect less than 1 person in 10 and more than 1 person in 100)
- Irritation or discomfort in the inside of the nose – you may also get streaks of blood when you blow your nose. This may be due to nasal ulceration.

If any of the side effects gets serious or troublesome, or if you notice any side effects not listed in this leaflet: Tell your doctor or pharmacist.

5. HOW TO STORE FLUTICASONE FUROATE GSK

Keep out of the reach and sight of children.

Do not use Fluticasone furoate GSK after the expiry date which is stated on the label and carton. The expiry date refers to the last day of the month. Fluticasone furoate GSK nasal spray should be used within 2 months after first opening.

Do not refrigerate or freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

**What Fluticasone furoate GSK contains**
The active substance is fluticasone furoate. Each spray delivers 27.5 micrograms of fluticasone furoate.
The other ingredients are glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride, disodium edetate, purified water.

**What Fluticasone furoate GSK looks like and contents of the pack**
The medicine is a white nasal spray suspension contained in an amber glass bottle, fitted with a pump.
The bottle is in an off-white plastic casing with a light blue cap and side-actuated lever. The casing has a window for viewing the bottle contents. Fluticasone furoate GSK is available in pack sizes 30, 60 and 120 sprays.

**Marketing authorisation holder**
Marketing authorisation:
Glaxo Group Ltd
Greenford, Middlesex, UB6 0NN
United Kingdom

**Manufacturer:**
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