

**FLUTICASONE PROPIONATE 50 MICROGRAMS NASAL
SPRAY, SUSPENSION (FLUTICASONE PROPIONATE)**

PL 00106/0017

UKPAR

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FLUTICASONE PROPIONATE 50 MICROGRAMS NASAL SPRAY, SUSPENSION (FLUTICASONE PROPIONATE)

PL 00106/0017

LAY SUMMARY

The MHRA granted Edinburgh Pharmaceutical Industries Limited a Marketing Authorisation (licence) for the medicinal product Fluticasone propionate 50 micrograms nasal spray, suspension (PL 00106/0017) on 16th January 2006. This prescription only medicine (POM) is used to prevent and treat seasonal allergic rhinitis (such as hayfever) or perennial rhinitis.

Fluticasone propionate nasal spray contains the active ingredient fluticasone propionate, a corticosteroid with an anti-inflammatory action which helps to reduce swelling and irritation in the nose.

This application is a duplicate of a previously granted application for Flixonase Aqueous Nasal Spray (PL 10949/0036) and, as such, these products can be used interchangeably.

No new or unexpected safety concerns arose from these simple applications and it was, therefore, judged that the benefits of taking Fluticasone propionate nasal spray outweigh the risks, hence a Marketing Authorisation has been granted.

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Fluticasone propionate 50 micrograms nasal spray, suspension (PL 00106/0017) to Edinburgh Pharmaceutical Laboratories Ltd on 16 January 2006. The product is a prescription only medicine.

The application was submitted as an informed consent abridged application according to article 10.1(a)(i) of Directive 2001/83/EC, cross-referring to Flixonase Aqueous Nasal Spray (PL 10949/0036). The cross-reference application was granted on 15th September 1995 as a change of ownership from PL 00045/0153, which was submitted as a full application according to article 4.8 of Directive 65/65/EC, as amended. Based on the review of the data on quality, safety and efficacy the UK granted a marketing authorisation for this medicinal product on 8th March 1990.

No new data was submitted nor was it necessary for this simple application, as the data is identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

The product contains the active ingredient fluticasone propionate which is a corticosteroid with anti-inflammatory properties. Fluticasone propionate nasal spray is indicated for the prophylaxis and treatment of seasonal allergic rhinitis (including hay fever) and perennial rhinitis.

PHARMACEUTICAL ASSESSMENT

INTRODUCTION

This is an abridged application made under Article 10.1(a)(i) of EC Directive 2001/83 and is considered to be an identical product to that of PL 10949/0036 (Flixonase Aqueous Nasal Spray). The licence is held by GlaxoSmithKline Limited, granted 15th September 1995. A letter from GlaxoSmithKline Limited is provided authorising cross-reference to its licence. Edinburgh Pharmaceutical Industries Limited is a member of the GlaxoSmithKline group of companies.

EXPERT REPORTS

Satisfactory statements provided.

MARKETING AUTHORISATION APPLICATION (MAA)

The MAA form is satisfactory and consistent with the cross-reference product.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPC supplied is satisfactory and consistent with the cross-reference product.

LABELLING

The labels supplied are satisfactory and consistent with the cross-reference product.

PATIENT INFORMATION LEAFLET (PIL)

The PIL supplied is satisfactory and consistent with the cross-reference product.

RECOMMENDATION

Grant of a Marketing Authorisation is acceptable.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with these applications and none are required for an application of this type.

CLINICAL ASSESSMENT

As these are duplicate applications for PL 10949/0036, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for these applications is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for applications of this type.

EFFICACY

Fluticasone propionate is a well known drug and has been used for the prophylaxis and treatment of seasonal allergic rhinitis and perennial rhinitis for many years. This application is identical to the approved marketing authorisation for Flixonase nasal spray (PL 19049/0036) which underwent a change of ownership from PL 00045/0153, in which the applicant demonstrated the efficacy of the Fluticasone propionate nasal spray.

No new or unexpected safety concerns arise from these applications.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product and, as such, can be used interchangeably. Extensive clinical experience with fluticasone propionate is considered to have demonstrated the therapeutic value of the compound. The risk benefit is therefore considered to be positive.

**FLUTICASONE PROPIONATE 50 MICROGRAMS NASAL
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STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application on 31/03/2004.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 19/05/2004.
3	Following assessment of the application the MHRA requested further information on 16/09/2004, 08/07/2005 and 07/12/2005
4	The applicant responded to the MHRA's requests, providing further information on 06/06/2005, 03/10/2005, and 08/12/2005.
5	The application was determined on 16/01/2006

**FLUTICASONE PROPIONATE 50 MICROGRAMS NASAL
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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

FLUTICASONE PROPIONATE 50 MICROGRAMS NASAL SPRAY, SUSPENSION (FLUTICASONE PROPIONATE)

PL 00106/0017

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fluticasone propionate 50 micrograms nasal spray, suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluticasone propionate 0.05% w/w. Each metered dose contains 50 micrograms of fluticasone propionate. For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, suspension. A white opaque suspension supplied in a glass bottle fitted with a metered atomising pump.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

The prophylaxis and treatment of seasonal allergic rhinitis (including hay fever) and perennial rhinitis. Fluticasone propionate has potent anti-inflammatory activity but when used topically on the nasal mucosa has no detectable systemic activity.

4.2. Posology and method of administration

For nasal use

Shake gently before use. For practical details on operation and cleaning procedures see the Patient Information Leaflet.

Adults and children over 12 years of age:

For the prophylaxis and treatment of seasonal allergic rhinitis and perennial rhinitis. Two sprays into each nostril once a day, preferably in the morning. In some cases

two sprays into each nostril twice daily may be required. Once symptoms are under control a maintenance dose of one spray per nostril once a day may be used. If symptoms recur the dosage may be increased accordingly. The minimum dose should be used at which effective control of symptoms is maintained. The maximum daily dose should not exceed four sprays into each nostril.

Elderly patients:

The normal adult dosage is applicable.

Children under 12 years of age:

For the prophylaxis and treatment of seasonal allergic rhinitis and perennial rhinitis in children aged 4-11 years a dose of one spray into each nostril once daily preferably in the morning is recommended. In some cases one spray into each nostril twice daily may be required. The maximum daily dose should not exceed two sprays into each nostril. The minimum dose should be used at which effective control of symptoms is maintained.

For full therapeutic benefit regular usage is essential. The absence of an immediate effect should be explained to the patient, as maximum relief may not be obtained until after 3 to 4 days of treatment.

4.3. Contraindications

Hypersensitivity to any of its ingredients.

4.4. Special warnings and precautions for use

Local infections: infections of the nasal airways should be appropriately treated but do not constitute a specific contra-indication to treatment with Fluticasone propionate 50 micrograms nasal spray, suspension.

The full benefit of Fluticasone propionate 50 micrograms nasal spray, suspension may not be achieved until treatment has been administered for several days.

Care must be taken while transferring patients from systemic steroid treatment to Fluticasone propionate 50 micrograms nasal spray, suspension if there is any reason to suppose that their adrenal function is impaired.

Although Fluticasone propionate 50 micrograms nasal spray, suspension will control seasonal allergic rhinitis in most cases, an abnormally heavy challenge of summer allergens may in certain instances necessitate appropriate additional therapy.

Systemic effects of nasal corticosteroids may occur particularly at high doses prescribed for prolonged periods. These effects vary between patients and different

corticosteroids (please refer to pharmacokinetic and pharmacodynamic information).

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.

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.

Ritonavir can greatly increase the concentration of fluticasone propionate in plasma. Therefore, concomitant use should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects. There is also an increased risk of systemic side effects when combining fluticasone propionate with other potent CYP3A inhibitors (see 4.5 Interaction with Other Medicinal Products and Other Forms of Interaction).

4.5. Interactions with other medicinal products and other forms of interaction

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

In an interaction study in healthy subjects with intranasal fluticasone propionate, ritonavir (a highly potent cytochrome P450 3A4 inhibitor) 100 mg b.i.d. increased the fluticasone propionate plasma concentrations several hundred fold, resulting in markedly reduced serum cortisol concentrations. Cases of Cushing's syndrome and adrenal suppression have been reported. The combination should be avoided unless the benefit outweighs the increased risk of systemic glucocorticoid side-effects.

In a small study using inhaled fluticasone propionate in healthy volunteers, the slightly less potent CYP3A inhibitor ketoconazole increased the exposure of fluticasone propionate after a single inhalation by 150%. This resulted in a greater reduction of plasma cortisol as compared with fluticasone propionate alone. Co-treatment with other potent CYP3A inhibitors, such as itraconazole, is also expected to increase the systemic fluticasone propionate exposure and the risk of systemic side-effects. Caution is recommended and long-term treatment with such drugs should if possible be avoided.

4.6. Pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development, including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. It should be noted, however, that the foetal changes in animals occur after relatively high systemic exposure; direct intranasal application ensures minimal systemic exposure.

As with other drugs the use of Fluticasone propionate 50 micrograms nasal spray, suspension during human pregnancy requires that the possible benefits of the drug be weighed against the possible hazards.

The secretion of fluticasone propionate in human breast milk has not been investigated. Subcutaneous administration of fluticasone propionate to lactating laboratory rats produced measurable plasma levels and evidence of fluticasone propionate in the milk. However, following intranasal administration to primates, no drug was detected in the plasma, and it is therefore unlikely that the drug would be detectable in milk. When Fluticasone propionate 50 micrograms nasal spray, suspension is used in breast feeding mothers the therapeutic benefits must be weighed against the potential hazards to mother and baby.

4.7. Effects on ability to drive and use machines

None reported.

4.8. Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1000$) and very rare ($< 1/10,000$) including isolated reports. Very common, common and uncommon events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data. In assigning adverse event frequencies, the background rates in placebo groups were not taken into account.

System Organ Class	Adverse Event	Frequency
Immune system disorders	Hypersensitivity reactions with the following manifestations:	
	Cutaneous hypersensitivity reactions	Very rare
	Angioedema (mainly facial and oropharyngeal oedema)	Very rare
	Respiratory symptoms (bronchospasm)	Very rare
	Anaphylactic reactions	Very rare
Nervous system disorders	Headache, unpleasant taste, unpleasant smell.	Common

Eye disorders	Glaucoma, raised intraocular pressure, cataract These events have been identified from spontaneous reports following prolonged treatment.	Very rare
Respiratory, Thoracic & Mediastinal disorders	Epistaxis	Very common
	Nasal dryness, nasal irritation, throat dryness, throat irritation.	Common
	Nasal septal perforation.	Very rare

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

As with other nasal sprays, dryness and irritation of the nose and throat, and epistaxis have been reported. Nasal septal perforation has also been reported following the use of intranasal corticosteroids.

Systemic effects of some nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods.

4.9. Overdose

There are no data available on the effects of acute or chronic overdosage with Fluticasone propionate 50 micrograms nasal spray, suspension. Intranasal administration of 2 mg fluticasone propionate twice daily for seven days to healthy human volunteers has no effect on hypothalamo-pituitary-adrenal (HPA) axis function.

Inhalation or oral administration of high doses of corticosteroids over a long period may lead to suppression of HPA axis function.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Fluticasone propionate causes little or no hypothalamic-pituitary-adrenal axis suppression following intranasal administration.

Following intranasal dosing of fluticasone propionate, (200mcg/day) no significant change in 24h serum cortisol AUC was found compared to placebo (ratio 1.01, 90% CI 0.9-1.14).

ATC code: R01AD08

5.2. Pharmacokinetic properties

Absorption: Following intranasal dosing of fluticasone propionate, (200mcg/day) steady-state maximum plasma concentrations were not quantifiable in most subjects (<0.01ng/mL). The highest Cmax observed was 0.017ng/mL. Direct absorption in the nose is negligible due to the low aqueous solubility with the majority of the dose being eventually swallowed. When administered orally the systemic exposure is <1% due to poor absorption and pre-systemic metabolism. The total systemic absorption arising from both nasal and oral absorption of the swallowed dose is therefore negligible.

Distribution: Fluticasone propionate has a large volume of distribution at steady-state (approximately 318L). Plasma protein binding is moderately high (91%).

Metabolism: Fluticasone propionate is cleared rapidly from the systemic circulation, principally by hepatic metabolism to an inactive carboxylic acid metabolite, by the cytochrome P450 enzyme CYP3A4. Swallowed fluticasone propionate is also subject to extensive first pass metabolism. Care should be taken when co-administering potent CYP3A4 inhibitors such as ketoconazole and ritonavir as there is potential for increased systemic exposure to fluticasone propionate.

Elimination: The elimination rate of intravenous administered fluticasone propionate is linear over the 250-1000mcg dose range and are characterized by a high plasma clearance (CL=1.1L/min). Peak plasma concentrations are reduced by approximately 98% within 3-4 hours and only low plasma concentrations were associated with the 7.8h terminal half-life. The renal clearance of fluticasone propionate is negligible (<0.2%) and less than 5% as the carboxylic acid metabolite. The major route of elimination is the excretion of fluticasone propionate and its metabolites in the bile.

5.3. Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glucose anhydrous
Microcrystalline Cellulose
Carboxymethylcellulose Sodium
Phenylethyl Alcohol
Benzalkonium Chloride
Polysorbate 80
Purified Water

6.2. Incompatibilities

None reported

6.3. Shelf life

24 months

6.4. Special precautions for storage

Do not store above 30°C.

6.5. Nature and contents of container

Fluticasone propionate 50 micrograms nasal spray, suspension is supplied in an amber glass bottle fitted with a metering, atomising pump. Packs of 120 and 150 metered sprays are registered.

6.6. Instruction for use and handling

Shake gently before use.

7. MARKETING AUTHORISATION HOLDER

Edinburgh Pharmaceutical Industries Limited
Irvine
Ayreshire
Scotland KA11 5AP

8. MARKETING AUTHORISATION NUMBER

PL 00106/0017

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/01/2006

10. DATE OF REVISION OF THE TEXT

FLUTICASONE PROPIONATE 50 MICROGRAMS NASAL SPRAY, SUSPENSION (FLUTICASONE PROPIONATE)

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PRODUCT INFORMATION LEAFLET



Fluticasone propionate 50 micrograms nasal spray, suspension

Patient Information Leaflet for Fluticasone propionate 50 micrograms nasal spray, suspension (fluticasone propionate)

Your doctor has decided to prescribe Fluticasone propionate 50 micrograms nasal spray, suspension as part of your treatment.

This leaflet tells you about Fluticasone propionate 50 micrograms nasal spray, suspension and how to use it. Please read it carefully and keep it until you have finished the medicine.

WHAT IS FLUTICASONE PROPIONATE 50 MICROGRAMS NASAL SPRAY, SUSPENSION?

Fluticasone propionate 50 micrograms nasal spray, suspension contains 50 micrograms of the active ingredient fluticasone propionate in each spray. It also contains other substances needed to make a stable suspension which will not go off. These are microcrystalline cellulose, sodium carboxymethylcellulose, glucose anhydrous, polysorbate 80, purified water and the preservatives benzalkonium chloride and phenylethylalcohol. Each bottle of Fluticasone propionate 50 micrograms nasal spray, suspension provides 150 sprays.

WHO MAKES YOUR MEDICINE?

Fluticasone propionate 50 micrograms nasal spray, suspension is manufactured by Glaxo Operations UK Ltd, Harmire Road, Barnard Castle, Co. Durham, DL12 8DT United Kingdom. The marketing authorisation is held by Edinburgh Pharmaceutical Industries Limited, Irvine, Ayrshire KA11 5AP.

HOW YOUR MEDICINE WORKS

Fluticasone propionate is a corticosteroid (steroid for short) which has an anti-inflammatory action. The tiny amounts sprayed into your nose help to reduce swelling and irritation. Fluticasone propionate should not be confused with anabolic steroids misused by some athletes and taken as tablets or injection.

USES

Fluticasone propionate 50 micrograms nasal spray, suspension is used to prevent and treat seasonal allergic rhinitis (e.g. hayfever) and perennial rhinitis in adults and children aged 4 years and over.

When you have rhinitis, the inside of your nose becomes swollen and itchy. This often occurs during the early summer when it is caused by breathing in pollens from grasses or trees and is called hayfever. Some people get problems all the year round and this is called perennial rhinitis. It is often due to house dust mites or animals such as cats or dogs.

When you spray Fluticasone propionate 50 micrograms nasal spray, suspension into your nose, it helps to relieve the itching, sneezing and blocked or runny nose.

MAKE SURE THAT THIS MEDICINE IS SUITABLE FOR YOU

TELL YOUR DOCTOR BEFORE STARTING TO TAKE THIS MEDICINE

* if you have ever had to stop taking this or another medicine for this illness because you were allergic to it or it caused problems,

* if you are pregnant (or intending to become pregnant),

* if you are breast-feeding a baby,

* if you have ever had an operation on your nose,

* if you have recently been treated with injected steroids or if you have been taking oral steroids for a long time.

Sometimes this medicine may not be suitable and your doctor may want to give you something different.

In some cases, Fluticasone propionate 50 micrograms nasal spray, suspension may not be suitable to use with other medicines so be sure you tell your doctor:

* if you are taking a type of antiviral medicine known as a protease inhibitor (e.g. ritonavir),

* if you are taking certain medicines used to treat fungal infections (e.g. ketoconazole).

Check with your pharmacist or doctor if you are not sure.

Make sure that your doctor knows what other medicines you are taking, including any you have bought from the chemist. Remember to take these medicines with you if you have to go into hospital.

USING YOUR NASAL SPRAY

- * Follow the instructions shown later in the leaflet. If you have any problems, tell your doctor or pharmacist.
- * Make sure you know **HOW**, **WHEN** and **HOW MANY** sprays you should use. Your doctor should have told you and the instructions should be on the pharmacist's label. If they are not, or you are not sure, ask your doctor or pharmacist.
- * **ONLY USE IN YOUR NOSE**

DOSE

- * **For adults and children aged 12 and over: the usual starting dose is TWO sprays into each nostril ONCE daily, preferably in the morning. Your doctor may advise you to increase this to a maximum of TWO sprays TWICE daily.**
- * **As your symptoms become better, your doctor may advise you to use a lower dose of ONE spray into each nostril ONCE a day. If your symptoms get worse again, your dose may be increased back again to the starting dose.**
- * **For children aged 4-11 years: the usual dose is ONE spray into each nostril ONCE daily, preferably in the morning. Your doctor may advise you to increase this to ONE spray into each nostril TWICE daily.**
- * **Your doctor will prescribe the lowest dose of Fluticasone propionate 50 micrograms nasal spray, suspension that will best control your symptoms.**
- * **DO NOT** take a larger dose or use your nasal spray more often than your doctor advises.
- * It takes a few days for this medicine to work and it is **VERY IMPORTANT THAT YOU USE IT REGULARLY. DO NOT STOP TREATMENT** even if you feel better unless told to do so by your doctor.
- * If you also have itchy, watery eyes, you should tell your doctor. He or she may give you an extra medicine to treat your eyes. Be careful not to confuse them, particularly if the second medicine is eye drops.



IF YOU MISS A DOSE

- * If you miss a dose, just take the next dose when it is due.

IF YOU TAKE TOO MUCH

- * Tell your doctor if you accidentally take more than you were told to.

AFTER USING YOUR NASAL SPRAY

- * You may sometimes sneeze a little after using this spray but this soon stops. Very occasionally you may experience an unpleasant taste or smell.
- * If you are using high doses of Fluticasone propionate 50 micrograms nasal spray, suspension, you may require extra steroids in times of extreme stress, or during admission to hospital after a serious accident or injury, or before a surgical operation. Your doctor may decide to give you extra steroid medication during this period as tablets or injection if you are in hospital.

SIDE EFFECTS

Most people do not have any problems after using this spray.

- * If your nose or throat becomes painful or if you have a bad nose bleed after using the nasal spray, stop using your Fluticasone propionate 50 micrograms nasal spray and tell your doctor as soon as possible.
- * Just after using the spray some people get
 - headaches
 - sneezing
 - an unpleasant taste or smell
 - irritation and/or dryness of the nose and throat.
- * Very rarely people have problems with their eyes after using the nasal spray. If you experience pain or blurred vision, tell your doctor as soon as possible.
- * There have been very rare reports of a severe allergic reaction to this medicine. If you suddenly develop a rash, swelling (usually of the face, lips or tongue) or difficulty with your breathing, stop using your Fluticasone propionate 50 micrograms nasal spray, suspension and contact your doctor IMMEDIATELY.
- * In very rare instances, treatment with some nasal corticosteroids may affect the normal production of steroids in the body. This is more likely to happen if high doses are being used over a long period of time. One of the rare effects is that children may grow more slowly than others.

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LABELLING

