FLIXONASE 0.05% NASAL SPRAY

(fluticasone propionate)

PL 00079/0692

UKPAR

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This is a summary of the public assessment report (PAR) for Flixonase 0.05% Nasal Spray (PL 00079/0692). It explains how Flixonase 0.05% Nasal Spray was assessed and its authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Flixonase 0.05% Nasal Spray.

For practical information about using Flixonase 0.05% Nasal Spray, patients should read the package leaflet or contact their doctor or pharmacist.

What is Flixonase 0.05% Nasal Spray and what is it used for?

Flixonase 0.05% Nasal Spray contains the active ingredient fluticasone propionate. Flixonase 0.05% Nasal Spray is prescribed to treat and prevent the allergic symptoms of hayfever and other airborne allergies, such as; pet, house dust mite and mould spore allergies. It relieves symptoms including sneezing, itchy and watery eyes, runny, itchy or blocked up nose, for up to 24 hours.

This medicine is identical to Flixonase Allergy Nasal Spray/Pirinase Hayfever 0.05% Nasal Spray, which was originally authorised in the UK to Glaxo Wellcome UK Limited on 30 April 2002 (PL 10949/0360). Following a subsequent change of ownership procedure, the current marketing authorisation holder since 14 August 2007 is Beecham Group PLC (trading as GlaxoSmithKline Consumer Healthcare; PL 00079/0616). Beecham Group PLC has agreed that scientific data presented for Flixonase Allergy Nasal Spray/Pirinase Hayfever 0.05% Nasal Spray (PL 00079/0616) can be used for this application for Flixonase 0.05% Nasal Spray.

How is Flixonase 0.05% Nasal Spray used?

Flixonase 0.05% Nasal Spray can be obtained without a prescription from a pharmacy. It should only be used in the nose and should not be swallowed. Flixonase 0.05% Nasal spray reduces inflammation and swelling in the nose. It may take 3 to 4 days to build up to its maximum protective effect. To prevent the onset of symptoms, it is recommended to use Flixonase 0.05% Nasal Spray in the morning, before exposure to any allergy triggers.

How does Flixonase 0.05% Nasal Spray work?

Flixonase 0.05% Nasal Spray contains the active ingredient fluticasone propionate. Fluticasone propionate is a corticosteroid that, when used every day, has an anti-inflammatory action and works in a similar way to the body’s natural chemicals which control inflammation. This spray helps to control the body’s reactions to allergens (triggers).

How has Flixonase 0.05% Nasal Spray been studied?

This application is identical to the previously granted application for Flixonase Allergy Nasal Spray/Pirinase Hayfever 0.05% Nasal Spray (PL 00079/0616; Beecham
The Marketing Authorisation holder referred to data provided by Beecham Group PLC for the grant of Flixonase Allergy Nasal Spray/Pirinase Hayfever 0.05% Nasal Spray (PL 00079/0616) as a basis for the grant of an identical licence for Flixonase 0.05% Nasal Spray (PL 00079/0692).

**What are the benefits and risks of Flixonase 0.05% Nasal Spray?**

Flixonase 0.05% Nasal Spray is considered identical to previously authorised Flixonase Allergy Nasal Spray/Pirinase Hayfever 0.05% Nasal Spray (PL 00079/0616; Beecham Group PLC), with the same benefits and risks.

**Why is Flixonase 0.05% Nasal Spray approved?**

No new or unexpected safety concerns arose from this application. It was, therefore, considered that the benefits of Flixonase 0.05% Nasal Spray outweigh their risks; and the grant of a Marketing Authorisation was recommended.

**What measures are being taken to ensure the safe and effective use of Flixonase 0.05% Nasal Spray?**

A risk management plan has been developed to ensure that Flixonase 0.05% Nasal Spray is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Flixonase 0.05% Nasal Spray, including the appropriate precautions to be followed by healthcare professionals and patients.

**Other information about Flixonase 0.05% Nasal Spray**

A Marketing Authorisation was granted in the UK on 31 January 2014. For more information about treatment with Flixonase 0.05% Nasal Spray, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in March 2014.

The full PAR for Flixonase 0.05% Nasal Spray follows this summary.
FLIXONASE 0.05% NASAL SPRAY

(PL 00079/0692)

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation for the medicinal product Flixonase 0.05% Nasal Spray (PL 00079/0692) on 31 January 2014 to Beecham Group PLC (trading as GlaxoSmithKline Consumer Healthcare).

This application for Flixonase 0.05% Nasal Spray was submitted as an abridged simple application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Flixonase Allergy Nasal Spray/Pirinase Hayfever 0.05% Nasal Spray (PL 00079/0616; Beecham Group PLC), which was originally authorised in the UK to Glaxo Wellcome UK Limited on 30 April 2002 (PL 10949/0360). Following a subsequent change of ownership procedure, the current Marketing Authorisation Holder since 14 August 2007 is Beecham Group PLC (PL 00079/0616).

This medicine can be obtained without a prescription from a pharmacy (legal status P), and is indicated for the prophylaxis and treatment of allergic rhinitis including hay fever and that caused by other airborne allergens such as house dust mite and animal dander. Flixonase 0.05% Nasal Spray also provides symptomatic relief of sneezing, itchy and runny nose, itchy and watery eyes, nasal congestion and associated sinus discomfort.

The product contains the active ingredient fluticasone propionate. Fluticasone propionate is a glucocorticosteroid which has potent anti-inflammatory activity by acting via the glucocorticoid receptor. Fluticasone propionate has been shown to reduce inflammatory mediators in both the early and late phase reactions of allergic rhinitis.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00079/0692
PROPRIETARY NAME: Flixonase 0.05% Nasal Spray
ACTIVE(S): Fluticasone propionate
COMPANY NAME: Beecham Group PLC (trading as GlaxoSmithKline Consumer Healthcare).
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: P

1. INTRODUCTION
This is a simple, piggyback application for Flixonase 0.05% Nasal Spray submitted under Article 10c of Directive 2001/83/EC, as amended. The proposed MA holder is Beecham Group PLC (trading as GlaxoSmithKline Consumer Healthcare), 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

The application cross-refers to Flixonase Allergy Nasal Spray/Pirinase Hayfever 0.05% Nasal Spray (PL 00079/0616; Beecham Group PLC), which was originally authorised in the UK to Glaxo Wellcome UK Limited on 30 April 2002 (PL 10949/0360).

This current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The proposed name of the product is Flixonase 0.05% Nasal Spray. This product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Flixonase 0.05% Nasal Spray contains an aqueous suspension of 0.05% micronised fluticasone propionate. Each actuation contains 50 micrograms of fluticasone propionate.

The finished product is stored in an amber glass bottle which is fitted with a metering pump and a nasal applicator. Each bottle provides approximately 60 metered sprays.

The Marketing Authorisation Holder has stated that Flixonase 0.05% Nasal Spray is not intended for marketing. However, they have committed to providing the relevant licensing authority with the mock-ups for any pack size before marketing it in that country.

The proposed shelf-life for Flixonase 0.05% Nasal Spray (36 months) and the storage conditions (Do not store above 30°C) are consistent with the details registered for the cross-reference product.

2.3 Legal status
On approval, the product will be available without prescription from a pharmacy (legal status P).
2.4 Marketing authorisation holder/Contact Persons/Company
Beecham Group PLC (trading As GlaxoSmithKline Consumer Healthcare), 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch sizes are stated.

2.8 Finished product/shelf-life specification
The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
No materials of animal or human origin are included in this product. This is consistent with the cross-reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The proposed SmPC is consistent with the details registered for the cross-reference product.
6. **PATIENT INFORMATION LEAFLET (PIL)/CARTON**

   **PIL**
   The patient information leaflet has been prepared in line with the details registered for the cross-reference product.

   **Labelling**
   The proposed labelling is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. **CONCLUSIONS**

   The data submitted with this application are acceptable. From a quality perspective, a Marketing Authorisation should be granted.

   **NON-CLINICAL ASSESSMENT**

   No new non-clinical data have been supplied with this application and none are required for applications of this type.

   **CLINICAL ASSESSMENT**

   No new clinical data have been supplied with this application and none are required for applications of this type.
OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY
The important quality characteristics of Flixonase 0.05% Nasal Spray are identical to those of the already granted reference product. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

CLINICAL PHARMACOLOGY/EFFICACY
No new clinical pharmacology/efficacy data have been submitted with this application and none are required for an application of this type.

SAFETY
No new safety data have been submitted with this application and none are required for an application of this type.

No new or unexpected safety concerns arose from this application.

The SmPC, labelling and PIL are satisfactory.

Pharmacovigilance System and Risk Management Plan
The Pharmacovigilance System, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

A risk management plan has been developed to ensure that Flixonase 0.05% Nasal Spray is used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the package leaflet for Flixonase 0.05% Nasal Spray approved, including the appropriate precautions to be followed by healthcare professionals and patients.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with Flixonase 0.05% Nasal Spray is considered to have demonstrated the therapeutic value of the product. The benefit/risk is, therefore, considered to be positive.
FIXONASE 0.05% NASAL SPRAY
(PL 00079/0692)

STEPS TAKEN FOR ASSESSMENT

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<tr>
<td>1</td>
<td>The MHRA received the marketing authorisation application on 01 October 2012.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant, the MHRA considered the application valid on 16 October 2012.</td>
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<td>3</td>
<td>Following assessment of the application, the MHRA requested further information relating to the dossiers on 10 December 2012 and 05 July 2013.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 07 June 2013 and 31 October 2013.</td>
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<td>5</td>
<td>The application was determined on 31 January 2014.</td>
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FLIXONASE 0.05% NASAL SPRAY

(PL 00079/0692)

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

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<th>Application type</th>
<th>Scope</th>
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Summary of Product Characteristics and Patient Information Leaflet
The current approved UK versions of the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PILs) for these products is available on the MHRA website.
Labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
Carton

1. NAME OF THE MEDICINAL PRODUCT

Flixonase 0.05% Nasal Spray
Fluticasone Propionate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Flixonase 0.05% Nasal Spray is an aqueous spray containing 0.05% w/w fluticasone propionate (50 micrograms per spray).

3. LIST OF EXCIPIENTS

Also contains: dextrose; microcrystalline cellulose; carboxymethylcellulose sodium; polysorbate 80; purified water; dilute hydrochloric acid, preservatives: phenylethyl alcohol, benzalkonium chloride.

4. PHARMACEUTICAL FORM AND CONTENTS

Nasal spray.
60 sprays.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake gently before use.
Use only in the nose.
Please read the enclosed leaflet carefully before use.

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

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
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

GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K.

12. MARKETING AUTHORISATION NUMBER(S)

PL 00079/0692

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

P

15. INSTRUCTIONS ON USE

Prevents and relieves symptoms of airborne allergens including: pollen (hayfever); pet hair; dust mite; mould spores.

Also relieves nasal congestion.

Flixonase 0.05% Nasal Spray works to:

Help relieve allergy symptoms for up to 24 hours.

Help prevent the return of symptoms during the day.

Flixonase 0.05% Nasal Spray has a direct action to relieve allergy symptoms where they start.

How to use

Shake gently before use.

Use only in the nose.

Adults aged 18 years and over:

Usual dose: 2 sprays in each nostril, once a day. If symptoms improve use 1 spray in each nostril once a day. If symptoms are especially bad: 2 sprays in each nostril may be used twice a day. Once symptoms improve, go back to the usual dose.

Children: Not for use in children under 18 years.

DO NOT USE

more than 4 sprays in each nostril in a day.
for more than 3 months continuously without consulting your doctor.

**CONSULT YOUR DOCTOR**

before use, if you are pregnant or breast-feeding.

if your symptoms have not improved after using the spray for 7 days.

16. INFORMATION IN BRAILLE

Flixonase Nasal Spray
1. NAME OF THE MEDICINAL PRODUCT

Flixonase 0.05% Nasal Spray
Fluticasone Propionate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Nasal spray
60 sprays.

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Please read enclosed leaflet before use.

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Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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
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Adults aged 18 and over:
Usual dosage: 2 sprays in each nostril, once a day.
Not for use in children under 18 years.
Shake gently before use.
Use only in the nose.
Do not use more than 4 sprays in each nostril in a day.

16. INFORMATION IN BRAILLE