Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Prescription Only Medicine to Pharmacy Reclassification

Pirinase Allergy 0.05% Nasal Spray

Fluticasone Propionate (0.05%)

PL 44673/0099 - 0009

GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED

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The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK Government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK, and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side effects to any drug or vaccine can be reported to MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme (https://yellowcard.mhra.gov.uk/).

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1 Introduction

Pirinase Allergy 0.05% Nasal Spray can be used to prevent and treat allergic rhinitis, including hayfever. Allergic rhinitis is inflammation of the inside of the nose caused by an allergen. An allergen is a substance that causes an allergic response. Examples include pollen, dust, mould, or flakes of skin from certain animals. The nasal spray also provides relief of symptoms including sneezing, itchy and runny nose, itchy and watery eyes, nasal congestion and associated sinus discomfort.

Each spray contains 50 micrograms of fluticasone propionate.

The licence holder[1], GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, applied to introduce a pack size of 120 metered sprays with a Pharmacy (P) legal status (see Background for definition).

The Medicines and Healthcare Products Regulatory Agency (MHRA) considers this product sufficiently safe to be sold as a pharmacy medicine. This report outlines the evidence that the MHRA reviewed and which led to the decision to approve the application.

2 Background

Fluticasone propionate is a steroid (specifically a glucocorticosteroid) that acts to reduce inflammation which is a sign of allergic rhinitis including hay fever.

A Prescription Only Medicine (POM) must be prescribed by a doctor or other authorised health professional and it must be dispensed from a pharmacy or from another specifically licensed place. Pharmacy medicines can be supplied without prescription only from pharmacies, by or under the supervision of a pharmacist.

Fluticasone propionate aqueous nasal spray (FPANS) was first approved in 1990 as a prescription product for the prevention and treatment of allergic rhinitis. In the UK, the nasal spray was approved with a P legal status in May 2002 with a maximum pack size of 60 metered sprays. In 2015, the product 'Pirinase Hayfever Relief for Adults 0.05% Nasal Spray' was reclassified from P to GSL (General Sales List) with a maximum pack size of 60 metered sprays. General Sales List medicines can be sold or supplied in other retail outlets other than pharmacies by someone who is not a pharmacist.

3 Proposed Terms of Reclassification

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited proposed to make Pirinase Allergy 0.05% Nasal Spray available through pharmacies with the following terms of reclassification:

a) Pack size: 120 metered sprays

[1] A licence holder or marketing authorisation holder is the company with legal authorisation to make the medicine available to patients.

b) Used for the preventative action and treatment of allergic rhinitis including hay fever and that caused by other airborne allergens such as house dust mite and animal dander. The nasal spray also provides symptomatic relief of sneezing, itchy and runny nose, itchy and watery eyes, nasal congestion and associated sinus discomfort
c) Dose: (Adults aged 18 and over) 2 sprays into each nostril once a day. If symptoms improve use 1 spray in each nostril once a day. If symptoms are especially bad, use 2 sprays in each nostril twice a day. Once symptoms improve, go back to the usual dose. Do not use more than 4 sprays in each nostril a day.
d) Route of administration: Intranasal (use only in the nose)
e) Strength: Each spray contains 50 micrograms of fluticasone propionate
f) Duration of treatment: Not to be used for more than 3 months continuously without consulting a doctor. Treatment should be stopped or the advice of a doctor sought if an improvement is not seen within 7 days.

4 Prescription Only Medicine (POM) Criteria

To be reclassified from POM to P, a medicine must:

- be unlikely to be a direct or indirect danger to human health when used without the supervision of a doctor, even if used correctly
- be generally used correctly (i.e. not frequently or to a wide extent used correctly)
- not contain substances or preparations of substances where the activity of the product or its side effects require further investigation
- not normally be prescribed by a doctor for injection (parenteral administration)

These criteria are set out in the Human Medicines Regulations 2012, regulation 62(3).

5 Assessment of suitability for Pharmacy availability

The MHRA assessed the application against the POM criteria as stated in section 4.

5.1 POM Criteria 1

5.1.1 Direct Danger

'Direct danger' means that a danger may be present if the product causes adverse reactions that are important.

It is considered that Pirinase Allergy 0.05% is already well established in the pharmacy setting, and the risks of direct danger are not expected to increase due to the introduction of a larger pack size.
The post-marketing data provided by the applicant shows that there were only 24 adverse event reports during the 23 years of data capture. This almost equates to one adverse event report per year of reporting which is considered to be relatively low.

With regards to the risk of prolonged use, the 120 metered spray pack size can provide 30 days of supply when used at the recommended dose, and up to 60 days of use if used at the lowest dose. This is still one month less than the maximum duration of 3 months before medical advice should be sought,

which is advised in the product information. Considering the duration of allergic rhinitis, particularly for those suffering from seasonal allergic rhinitis (hayfever) which can last for a few months, the increase in pack size would not be considered to contribute to an increase in adverse events. The references provided by the applicant also support this conclusion.

There are currently other nasal steroid sprays which are available as a pharmacy medicine with pack sizes that provide a similar number of days of treatment when used as the lowest dose.

5.1.2 Indirect Danger

"Indirect dangers" are considered to be when treatment might mask an underlying condition that requires medical attention.

Pirinase Allergy 0.05% Nasal Spray is already classified as a P medicine and therefore the risk of supply of the product for a different diagnosis has already been considered. A larger pack size is not expected to increase the risk of an indirect danger in this aspect as no changes to the indications are being proposed as part of this application.

Whilst the larger pack size of 120 sprays can provide a longer duration of treatment, the label and leaflet[2] advise to consult a doctor after 7 days if symptoms have not improved and to not use continuously for more than 3 months without consulting a doctor first. As the larger pack size can permit a duration of treatment of up to 60 days when used at the lowest dose, the risk of masking an underlying treatment is considered to be low.

The product's summary of product characteristics (SPC)[3] states that using the nasal spray with medicines such as those used for HIV may result in an increased amount of fluticasone propionate that the user is exposed to. To reduce this risk and to align with the product information of General Sales List (GSL) fluticasone propionate preparations, the label was updated to include the warning of this combined use.

5.2 POM Criteria 2

5.2.1 Incorrect Use

There is no evidence that Pirinase Allergy 0.05% Nasal Spray is frequently and to a very wide extent used incorrectly. Due to the low amount of medicine being absorbed from the nasal spray, the risk of abuse and the risk of dependence are expected to be very low. There is no indication of significant misuse of this product since it was reclassified to P in 2002.

5.3 POM Criteria 3

5.3.1 Activity and/or adverse reactions require further investigation

This medicinal product contains only fluticasone propionate as the active ingredient. The activity of and adverse reactions to Pirinase Allergy 0.05% Nasal Spray are well established and do not require further investigation.

[2] The label and leaflet (patient information leaflet) provide information to patients about the medicine, including information about how to use them.

[3] The summary of product characteristics is a description of a medicinal product's properties and the conditions attached to its use.

5.4 POM Criteria 4

5.4.1 Is normally prescribed as an injection

This product is for nasal use only, so this criterion does not apply.

6 Further Details on the Application

The application contains a risk management plan (RMP). RMPs are documents that contain information on a medicine's safety profile and one or more of the following:

- how any risks identified in the safety profile will be prevented or minimised in patients
- plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine
- risk factors for side effects
- measuring the effectiveness of measures taken to prevent or minimise risks.

The risk identified specific to this reclassification involves the potential for overuse of the product. However, the warnings on the label relevant to the risk of overuse are considered adequate in informing consumers on correct product use and no additional risk minimisation measures are considered necessary. Also, as the product will be classified as a pharmacy medicine additional advice on correct use will also be available from the pharmacy staff.

The risk of combined use of the nasal spray with medicines used for HIV has also been minimised by inclusion of the appropriate warning on the label which is aligned with the warning included previously on the label of the GSL product information.

7. Reasons for not seeking advice from the Commission on Human Medicines[4]

No major issues were identified in the assessment of this application. The availability of a 120-metered spray pack size as a Pharmacy medicine would result in minimal changes based on the following reasons:

1. The proposed use of the medicine, dosing regimen, route of administration, strength, and duration of treatment are the same as the currently approved pack size of the 60 metered spray (P).
2. The pack size limits duration of use to 60 days when used at the minimum dose, which is still less than the maximum recommended duration of treatment (3 months) before medical advice should be sought.
3. There are other marketed nasal steroids with a P legal status which also provide a similar number of days when used at the minimum effective dose.
4. The product information has been updated to emphasise the warnings related to how this medicine should be used, duration of use and key interactions.

[4] The Commission on Human Medicines (CHM) advises ministers on the safety, efficacy and quality of medicinal products. Their views are sought on reclassifications when more complex or new reclassifications of medicines are being proposed.

8 Conclusion

The MHRA has taken the decision to approve Pharmacy legal status for the 120 metered spray pack size of Pirinase Allergy 0.05% Nasal Spray under the following conditions:

a) Pack size: 120 metered sprays
b) Used for the preventative action and treatment of allergic rhinitis including hay fever and that caused by other airborne allergens such as house dust mite and animal dander. The nasal spray also provides symptomatic relief of sneezing, itchy and runny nose, itchy and watery eyes, nasal congestion and associated sinus discomfort
c) Dose: (Adults aged 18 and over) 2 sprays into each nostril once a day. If symptoms improve use 1 spray in each nostril once a day. If symptoms are especially bad, use 2 sprays in each nostril twice a day. Once symptoms improve, go back to the usual dose. Do not use more than 4 sprays in each nostril a day.
d) Route of administration: intranasal (use only in the nose)
e) Strength: Each spray contains 50 micrograms of fluticasone propionate
f) Duration of treatment: Not to be used for more than 3 months continuously without consulting a doctor. Treatment should be stopped or the advice of a doctor sought if an improvement is not seen within 7 days.

Medicines and Healthcare products Regulatory Agency,
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