Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Prescription only medicine to Pharmacy Reclassification

Nasonex Allergy Control 0.05% Nasal Spray

PL 00010/0663 - 0001

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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 (http://www.mhra.gov.uk/yellowcard)

1. Background on deciding where medicines are available

The role of MHRA
MHRA regulates medicines and medical devices in the UK, on behalf of the UK Licensing Authority. This means that MHRA decides whether medicines are available:

- on prescription only - 'prescription only medicine' (POM)
- bought from pharmacies - 'pharmacy medicine' (P)
- bought from other shops - 'general sales list medicine' (GSL)

What is re-classification of a medicine?
Making a change on where a medicine is available is called 'reclassification'. This is sometimes referred to as 'switching'. To decide on this change, MHRA may:

- take advice from its committees of external experts
- take advice from a group ('stakeholder group') of health professionals and representatives of people affected by the classification change
- run a public consultation

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 (ie 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)

What evidence is needed?
A company or organisation can ask MHRA for a medicine to be available as a pharmacy medicine or a general sale medicine. To do this, they need to get together evidence to show that the medicine

a) is likely to be used appropriately, and
b) with relatively little danger to the public.

This evidence needs to focus on the risk to the public. This includes evidence on the possible abuse or misuse of the medicine. The evidence may include:

- clinical studies
- evidence showing acceptable level of side effects
- advice of experts
- views of relevant health professionals and their professional bodies
- views of relevant public associations and individuals with an interest in the medicine under consideration.

Who makes the final decision?
The final decision on whether to approve a change is made by the MHRA, on behalf of the UK Licensing Authority.

2. About Nasonex Allergy Control

Nasonex Allergy Control is a medicine to treat the symptoms of hayfever (also called seasonal allergic rhinitis (SAR)) and perennial allergic rhinitis (PAR) for those 18 years and over, for a period of not more than 3 months. This medicine is currently a Prescription Only Medicine.

Hayfever, which occurs at certain times of the year, is an allergic reaction caused by breathing in pollen from trees, grasses, weeds and also moulds and fungal spores. Perennial allergic rhinitis occurs throughout the year and symptoms can be caused by a sensitivity to a variety of things including house dust mite, animal hair, feathers and certain foods.

The Commission on Human Medicines has advised that this product can be available as a Pharmacy medicine. This report outlines the evidence that the MHRA reviewed which led to the decision to approve this application.

What is in Nasonex Allergy Control?
Nasonex Allergy Control is a nasal spray containing mometasone furoate.

This is the first application for a mometasone furoate product to be available without prescription.

What is mometasone furoate used for?
Mometasone furoate is one of a group of medicines called corticosteroids. When mometasone furoate is sprayed into the nose it can help to relieve inflammation (swelling and irritation of the nose), sneezing, itching and a blocked up or runny nose.

Who has made the proposal?
The licence-holder for Nasonex Allergy Control (Bayer PLC) applied to make this product available through Pharmacies.

What is the view of the Commission on Human Medicines?
The Commission on Human Medicines has advised that this product can be available as a Pharmacy medicine.

3. Proposed terms of reclassification

What are the details of this change?
Nasonex Allergy Control will be made available through Pharmacy outlets for:

- Nasal administration
- For the treatment of the symptoms of seasonal and perennial allergic rhinitis for those 18 years and over, for a period of not more than 3 months
- Maximum dose: 100mcg per nostril
- Maximum daily dose: 200mcg
- Maximum pack size: 9000mcg of mometasone furoate

4. How was the proposal assessed for Nasonex Allergy Control being available on as a Pharmacy medicine?

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

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

Assessment of suitability for Pharmacy availability
The MHRA assessed the application against these criteria for reclassification:

Direct danger
The most significant risks of serious adverse reactions with corticosteroids are generally due to the systemic effects when the medicine is taken by mouth and the drug is taken up into the blood stream and transported to other parts of the body. It is recognised that the nasal spray formulations

of corticosteroids are poorly absorbed from the nasal mucosa (the lining of the nose) and therefore the risk of systemic serious adverse reactions is low.

No significant drug-drug interactions (interactions between mometsone furoate and other drugs taken at the same time) of clinical importance have been identified for mometasone furoate and there is little potential for such interactions due to the low bioavailability (availability in the blood stream) of mometasone furoate after intranasal use. Therefore the danger of drug-drug interactions leading to adverse reactions is low for this product.

The Licence or Marketing Authorisation Holder (MAH) reports that during the 2-year period (01-Jan-2013 to 31-Dec-2014) in which mometasone furoate nasal spray has been available without a prescription in Sweden, the estimated patient exposure is 23,454,335 patient-treatment days. During this time, a total of 76 adverse event cases were received, reporting 149 events. The five most frequently reported events during this period were drug dose omission (not taking a dose of the medicine) (21), product quality issue (21), drug ineffective (7), headache (5) and off label use (use in circumstances for which the product is not licensed) (5). The benefit/ risk profile of mometasone furoate nasal spray remains positive.

The safety profile of mometasone does not differ significantly from other nasal corticosteroids already available over the counter (OTC) without prescription.

Indirect danger
Indirect danger to human health, even when the product is used correctly, could occur where treatment might mask or hide an underlying condition requiring medical attention and supervision. Use of the medicine might delay diagnosis and definitive treatment and jeopardise the chance of more successful therapy. Therefore it is important that the condition or symptoms, for which a medicinal product not subject to a medical prescription is indicated, can be correctly assessed by the patient and that the product can be used without medical supervision.

Seasonal allergic rhinitis (hay fever) and perennial allergic rhinitis are conditions which can be readily diagnosed by patients and are already accepted as suitable conditions for self-diagnosis and self-medication. Numerous treatments are already available OTC to treat the symptoms of allergic rhinitis including other nasal steroid sprays (beclomethasone, budesonide, flunisolide, triamcinolone), antihistamines (e.g. cetirizine, azelastine, chlorphenamine) and sodium cromoglycate. It is accepted that self-diagnosis of SAR and PAR has a low risk of masking underlying diseases.

In the event that the symptoms are misdiagnosed, the patient will be instructed, via the label and leaflet, to seek medical advice if improvement is not seen within 14 days.

Incorrect use – frequently and to a very wide extent
It is agreed that the risks of misuse are low and mometasone is not known to have abuse potential. Due to the low systemic availability, even if the contents of a whole bottle were used at once it is unlikely that clinically significant adverse events would occur.

There is no evidence that similar products already available OTC for hay fever and perennial allergic rhinitis are used incorrectly. Allergic rhinitis is readily self-diagnosed and the products to treat it are used appropriately.

Activity and/or adverse reactions require further investigation
This product has been used as a prescription product since 1997 and the activity and adverse reactions are well established therefore this criterion does not apply.

Is normally prescribed as an injection
This product is for nasal use only, so this does not apply.

5. Further details on the application

Risk Management Plan
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 RMP for this product has identified the main risks associated with the product and proposes how these will be managed in the product information (SmPC, labelling and patient information leaflet).

6. Consultation on Pharmacy availability

Consultation document ARM 92, which summarises the proposals on the POM to P reclassification of Nasonex Allergy Control, was posted on the gov.uk website on 21 November 2016. The deadline for comments was given as 12 December 2016. ARM 92 can be accessed via the following link:
https://www.gov.uk/government/consultations/proposal-to-make-nasonex-allergy-control-nasal-spray-available-without-prescription

Five responses were received. These are provided in their entirety through the above link. Four responses supported the proposal, one was unsure about the proposal.

Of these five responses received, four of these were from specified organisations, including Royal Pharmaceutical Society; Guild of Healthcare Pharmacists; Royal College of Physicians. One organisation wished to remain confidential. The remaining response was from a semi-retired freelance pharmacist and regulatory affairs consultant.

The four organisations agreed that the safety profile of Nasonex Allergy Control does not differ from other OTC nasal steroids and that there are no significant risks with this reclassification. The concerns from the respondent who was unsure focus around the use of mometasone in children – this product is not indicated in those under 18 therefore these comments are not relevant.

Overall, no new issues of concern have been raised in relation to Pharmacy availability of Nasonex Allergy Control. The responses raised minor concerns about the readability and layout of the product information. The patient information leaflet and label text and design have been amended as a result of this consultation.

7. Conclusion

Assessment of the responses to consultation on the application for Nasonex Allergy Control has revealed no new issues of concern in addition to those already considered by CHM and on which CHM were reassured. In light of the advice from the Commission on Human Medicines the Licensing Authority has taken the decision to approve Pharmacy legal status for Nasonex Allergy Control.

MHRA
July 2017