

**Response document for MHRA public consultation on the ANNEX 1
proposal to make Nasonex Allergy Control available in Pharmacies
Ref: ARM92**

Name: [redacted]

Your details:

Position (if applicable): [redacted]

Organisation (if applicable): Guild of Healthcare Pharmacists

Email: [redacted]

1. Do you consider that Nasonex Allergy Control should be available as a Pharmacy medicine?

Yes

Comments:

We support the view that Nasonex Allergy Control 0.05% Nasal Spray will be unlikely to be a direct or indirect danger to the public without the supervision of a doctor and that the safety profile of mometasone does not differ significantly from other nasal corticosteroids already available over the counter without prescription.

With the availability of OTC intranasal corticosteroids, patients are able to select an option for self-care. Although available evidence shows that the efficacy and safety profiles of intranasal corticosteroids are similar, patient preference based on formulation characteristics of specific OTC products should be taken into account when helping patients choose an intranasal product suitable for their needs. This is an ideal opportunity for individual patients to obtain advice from a pharmacist. It is important for pharmacists to be aware of the available OTC product options and their formulation characteristics, as formulation differences may affect patient experiences with a product. Having this knowledge, pharmacists can engage in a discussion with the patient to determine what is important to them in terms of formulation characteristics and provide guidance in selecting an intranasal spray. Pharmacists can also educate patients on when and how to use an OTC nasal spray e.g. intranasal sprays work best when used daily and may not provide maximum relief until they have been used consistently for several days. Also, pharmacists can provide instructions on priming the spray bottle and using proper spray technique.

2. Do you have any specific comments on the leaflet or the label provided in the public reclassification report for Nasonex Allergy Control?

Yes

Comments:

We believe that the leaflet should contain further details:

Under the list of '**Warnings and Precautions**', add –

- if you have eye or vision problems such as cataracts or glaucoma
- if you have been near someone who has chicken pox or measles

Patients should be informed that treatment with Nasonex Allergy Control may be associated with adverse reactions which include nasal septum perforation. Although perforation in the nasal passageway is rare it can occur if a patient sprays it onto the middle of the nose instead

of towards the outer wall. Due to inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal septum ulcers should not use a nasal corticosteroid until healing has occurred. Patients should be cautioned not to direct the spray directly onto the nasal septum.

Under '**How to use Nasonex Allergy Control**', change the last sentence from:
"Therefore you should continue regular use to achieve the full benefit of treatment" to:
"Therefore you should continue regular use each day without missing a dose to achieve the full benefit of treatment"

Under '**How to use your nasal spray**' – Step 1 should be "Wash your hands well"

Under '**How to store Nasonex Allergy Control**' add "Avoid prolonged exposure of the product to direct sunlight. Brief exposure to light, as with normal use, is acceptable."

3. Do you have any other comments on the reclassification?

No

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

No

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gsi.gov.uk) to arrive by **12th December 2016**. Contributions received after that date cannot be included in the exercise.