Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

# Nasonex Allergy Control 0.05% Nasal Spray

# Public Consultation

# Proposal to make available from Pharmacies

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)

Ref: ARM92

# Nasonex Allergy Control 0.05% Nasal Spray

# Proposal to make available from Pharmacies without prescription

## We want to know what you think

- Nasonex Allergy Control 0.05% Nasal Spray is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial allergic rhinitis (this occurs throughout the year).
- Nasonex Allergy Control is only at the moment available on prescription.
- We propose to make it available in pharmacies.
- The MHRA considers that this product can be available as a Pharmacy medicine.
- We want to know what you think about this change.

**Please tell us your views – please use the form at the end of this document.**

The deadline for comments is **12 December 2016**.

## In this document there is:

- A summary of the proposed change and the background
- A copy of the patient information leaflet and label proposed if the change goes ahead
- A form for your response

The full name of the medicine is Nasonex Allergy Control 0.05% Nasal Spray – in this document, we will call it ‘Nasonex Allergy Control.’

# Contents:



# Product details:

**Product name:** Nasonex Allergy Control 0.05% Nasal Spray

**Active substances:** Mometasone furoate monohydrate

**Licence holder:** Bayer PLC

**Route of sale/supply:** Current – on prescription (POM); Proposed – Pharmacy (P)

**Indication:** To treat the symptoms of seasonal allergic or perennial allergic rhinitis in adults.
**Marketing Authorisation Number:** PL 00010/0663 - 0001
**Consultation is open from:** 21/11/2016 – 12/12/2016

**Reference:** ARM92

**Contact:** reclassification@mhra.gsi.gov.uk

# 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 MHRA considers that this product can be made available as a Pharmacy medicine. This report outlines the background to this decision. Please tell us your views by using the response form at the end of this document (Annex 1). The deadline for comments is **12/12/2016**.

The patient information leaflet, label and summary of product characteristics are provided in Annex 2, 3 and 4.

**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.

## 3. Proposal to make Nasonex Allergy Control available as a Pharmacy medicine

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

**What are the details of this change?**
The application proposes to make Nasonex Allergy Control 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
- 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:

- 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)

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).

**Label and leaflet**
The patient information leaflet and label are provided in Annex 2 and 3.

**Summary of Product Characteristics**
The Summary of Product Characteristics is provided in Annex 4. This document is a description of Nasonex Allergy Control's properties and the conditions attached to its use. It is used as a reference by healthcare professionals.

## 6. What do you think?

- Nasonex Allergy Control 0.05% Nasal Spray is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial allergic rhinitis.
- Nasonex Allergy Control is only at the moment available on prescription.
- We propose to make it available in pharmacies.
- The MHRA considers that this product can be available as a Pharmacy medicine.
- We want to know what you think about this change.

**Please tell us your views – please use the form on the next page in Annex 1. Please respond by 12 December 2016.**

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

**ANNEX 1**

**Your details**

**Name:**

**Position (if applicable):**

**Organisation (if applicable):**

**Email:**

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

Yes ☐ No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

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

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

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

Yes ☐ Partially* ☐ No ☐

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

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 **12 December 2016.** Contributions received after that date cannot be included in the exercise.

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Package leaflet: Information for the user

# NASONEX®

## ALLERGY CONTROL 0.05% NASAL SPRAY

mometasone furoate

BAYER

**Please read this leaflet carefully before you start using this medicine because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine is available without prescription, but you still need to use Nasonex Allergy Control carefully to get the best results from it.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- **You must talk to your pharmacist or doctor if you do not feel better or if you feel worse after 14 days**

### What is in this leaflet



## 1. What Nasonex Allergy Control is and what it is used for

### What is Nasonex Allergy Control?

Nasonex Allergy Control nasal spray contains mometasone furoate, 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.

### What is Nasonex Allergy Control used for?

Nasonex Allergy Control is used to treat the symptoms of hayfever (also called seasonal allergic rhinitis) and perennial allergic rhinitis in adults aged 18 years and older.

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 (or dander), feathers and certain foods. Nasonex Allergy Control reduces the swelling and irritation in your nose thereby relieving sneezing, itching and a blocked-up or runny nose caused by hayfever or perennial allergic rhinitis.

## 2. What you need to know before you use Nasonex Allergy Control

### Do not use Nasonex Allergy Control

- if you are allergic (hypersensitive) to mometasone furoate or any of the other ingredients of this medicine (listed in section 6).
- if you have an untreated infection in your nose. Use of Nasonex Allergy Control during an untreated infection in your nose, such as herpes, can worsen the infection. You should wait until the infection is resolved before you start using the nasal spray.
- if you have recently had an operation on your nose or you have injured your nose. You should not use the nasal spray until your nose has healed.
- if you are under 18 years of age.
- if you are pregnant or breastfeeding without talking to your doctor first.
- for more than 3 months without consulting your doctor.

### Warnings and precautions

Talk to your doctor or pharmacist before using Nasonex Allergy Control
- if you have or have ever had tuberculosis.
- if you have any other infection.
- if you are taking other corticosteroid medicines, either by mouth or by injection.
- if you have cystic fibrosis.

While you are using Nasonex Allergy Control, talk to your doctor
- if your immune system is not functioning well (you have difficulty fighting infection) and you come into contact with anyone with measles or chickenpox. You should avoid coming into contact with anyone who has these infections.
- if you have an infection of the nose or throat.
- if you have persistent irritation to the nose or throat.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body.

### Other medicines and Nasonex Allergy Control

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines whilst using Nasonex Allergy Control.

Talk to your pharmacist before using this medicine if you are taking any prescribed corticosteroid medicines (including eczema creams, asthma inhalers, injections, nasal sprays and eye or nose drops). A few people may find that once they discontinue oral or injected corticosteroids they suffer from some undesirable effects, such as joint or muscular pain, weakness and depression. You may also seem to develop other allergies, such as itchy, watering eyes or patches of red and itchy skin. If you develop any of these effects, you should contact your doctor or pharmacist.

### Pregnancy and breast-feeding

Talk to your doctor before using Nasonex Allergy Control if you are pregnant, trying to become pregnant or are breastfeeding.

### Driving and using machines

There is no known information on the effect of Nasonex Allergy Control on the ability to drive or use machinery.

**Nasonex Allergy Control contains benzalkonium chloride**
Nasonex Allergy Control contains benzalkonium chloride which may cause nasal irritation.

## 3. How to use Nasonex Allergy Control

Always use Nasonex Allergy Control according to the instructions in this leaflet. You should check with your doctor or pharmacist if you are not sure. Do not use a larger dose or use the spray more often or for longer than instructed.

### Treatment of Hayfever and Perennial Allergic Rhinitis

**Adults (aged 18 years and over)**

**The usual dose is two sprays into each nostril once a day.**
- Once your symptoms are under control, you may reduce the dose to one spray into each nostril once a day.
- Use the lowest possible dose to control your symptoms.
- Do not use more than four sprays in a day.
- Do not use more than the recommended dose.

If your symptoms have not improved within 14 days, you should see your doctor or pharmacist.

In some patients Nasonex Allergy Control begins to relieve symptoms within 12 hours after the first dose; however full benefit of treatment may not be seen in the first two days. Therefore, you should continue regular use to achieve the full benefit of treatment.



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If you suffer badly from hayfever, you can start using Nasonex Allergy Control some days before the start of the pollen season, as this will help to prevent your hayfever symptoms from occurring.

**Children or adolescents under 18 years**
Do not use in children and adolescents under 18 years.

### Preparing your nasal spray for use

Your Nasonex Allergy Control Nasal Spray has a dust cap which protects the nozzle and keeps it clean. Remember to take this off before using the spray and to replace it after use.

If you are using the spray for the first time you need to "prime" the bottle by pumping the spray 10 times until a fine mist is produced:
1. Gently shake the bottle.
2. Put your forefinger and middle finger either side of the nozzle and your thumb underneath the bottle. **Do Not** pierce the nasal applicator.
3. Point the nozzle away from you and then press down with your fingers to pump the spray 10 times until a fine mist is produced.

If you have not used the spray for 14 days or more, you need to "re-prime" the bottle by pumping the spray 2 times until a fine mist is produced.

### How to use your nasal spray

1. Shake the bottle gently and remove the dust cap. (Figure 1)
2. Gently blow your nose.
3. Close one nostril and put the nozzle into the other nostril as shown. (Figure 2) Tilt your head forward slightly, keeping the bottle upright.
4. Start to breathe in gently or slowly through your nose and whilst you are breathing in squirt a spray of fine mist into your nose by pressing down ONCE with your fingers.
5. Breathe out through your mouth. Repeat step 4 to inhale a second spray in the same nostril if applicable.
6. Remove the nozzle from this nostril and breathe out through the mouth.
7. Repeat steps 3 to 6 for the other nostril (Figure 3).

Figure 1

Figure 2

Figure 3

After using the spray, wipe the nozzle carefully with a clean handkerchief or tissue and replace the dust cap.

Cleaning your nasal spray
- It is important to clean your nasal spray regularly, otherwise it may not work properly.
- Remove the dust cap and gently pull off the nozzle.
- Wash the nozzle and dust cap in warm water and then rinse under a running tap.
- **Do not try to unblock the nasal applicator by inserting a pin or other sharp object as this will damage the applicator and cause you not to get the right dose of medicine.**
- Allow the dust cap and nozzle to dry in a warm place.
- Push the nozzle back onto the bottle and replace the dust cap.
- The spray will need to be primed again with 2 sprays when first used after cleaning.

### If you use more Nasonex Allergy Control than you should

Tell your doctor or pharmacist if you accidentally use more than this leaflet recommends.

If you use steroids for a long time or in large amounts they may, rarely, affect some of your hormones.

### If you forget to use Nasonex Allergy Control

If you forget to use your nasal spray at the right time, use it as soon as you remember, then carry on as before. Do not take a double dose to make up for a forgotten dose.

### If you stop using Nasonex Allergy Control

In some patients Nasonex Allergy Control should begin to relieve symptoms 12 hours after the first dose; however full benefit of treatment may not be seen for up to two days. It is very important that you use your nasal spray regularly. If you stop treatment before the end of the allergy season your symptoms may reoccur.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Immediate hypersensitivity (allergic) reactions may occur after use of this product. These reactions may be severe. You should **stop taking** Nasonex Allergy Control and get **immediate medical help** if you experience symptoms such as:
- swollen face, tongue or pharynx
- trouble swallowing
- hives
- wheezing or trouble breathing

**Stop taking** the medicine and **tell your doctor** if you experience:
- eye problems such as pain or blurred vision.
- nasal problems such as pain and/or persistent bleeding.

When corticosteroid nasal sprays are used at high doses for long periods of time, side effects may occur due to the drug being absorbed in the body. The following side effects may occur:

Common side effects (may affect up to 1 in 10 people):
- headache
- sneezing
- nose bleeds [occurred very commonly (may affect more than 1 in 10 people) in people with nasal polyps receiving two sprays in each nostril twice a day]
- sore nose or throat
- ulcers in the nose
- respiratory tract infection

Not known (frequency cannot be estimated from the available data):
- increase in pressure in the eye (glaucoma) and/or cataracts causing visual disturbances
- damage to the partition in the nose which separates the nostrils
- changes in taste and smell
- difficulty in breathing and/or wheezing

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Nasonex Allergy Control

- Do not store the nasal spray above 25°C. Do not freeze it.
- The bottle should be used within 2 months of first opening.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Nasonex Allergy Control contains

- The active substance is mometasone furoate. Each spray contains 50 micrograms of mometasone furoate, as the monohydrate.
- The other ingredients are dispersible cellulose, glycerol, sodium citrate, citric acid monohydrate, polysorbate 80, benzalkonium chloride, purified water.

### What Nasonex Allergy Control looks like and contents of the pack

Nasonex Allergy Control is a nasal spray suspension.

Each 10g bottle contains 60 sprays, each 18g bottle contains 140 sprays. Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:
Bayer plc
Bayer House
Strawberry Hill
Newbury, Berkshire
RG14 1JA

The manufacturer is:
Schering-Plough Labo NV
Heist-op-den Berg
Belgium

This leaflet was last revised in October 2016.

Bayer



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REBRANDING CONFORM

13 3/32

7 3/4

6 13/16

Technical & Non Printing Items

Cutter  Guides

Colours

| PANTONE 122 C | PANTONE 321 C | PANTONE 323 C | PANTONE Cool Gray 9 C |
|---|---|---|---|
| 1 LTH | 2 LTH | 3 LTH | 4 LTH |

| Varnish | Brand |
|---|---|
| 5 LTH | 6 LTH |

| FONT SIZE PANEL | |
|---|---|
| Main Text (body copy): | 7.5 pt |
| Height (based on lower case x): | 1.37 mm |

NASONEX ALLERGY CONTROL 0.05% NASAL SPRAY

NASONEX®
ALLERGY CONTROL 0.05% NASAL SPRAY
mometasone furoate

Clinically proven to relieve the symptoms of:
- hayfever
- pet allergies
- mould allergies
- dust allergies

Also relieves nasal congestion

Non-Drowsy
Once Daily 24-Hour Nasal Spray for Adults

60 SPRAYS

BAYER

Free of CFC Propellants.
Do not store above 25°C.
Do not freeze.
Use within 2 months of first use.
**Do not pierce the nasal applicator.**

10g

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**NASONEX ALLERGY CONTROL 0.05% NASAL SPRAY**

**Please read the enclosed leaflet carefully before use.**

When allergy season starts, regain control of symptoms with **Nasonex Allergy Control** nasal spray. Its direct anti-inflammatory action works inside the nasal passages to treat and relieve allergy symptoms such as congestion, sneezing, runny nose, and itchy, watery eyes. Once a day dose of **Nasonex Allergy Control** provides up to 24 hours of effective relief.

The full benefit of treatment with **Nasonex Allergy Control** may take up to 2 days to develop.

If you suffer badly from hayfever you can start using **Nasonex Allergy Control** some days before the start of the pollen season. This allows **Nasonex Allergy Control** to reach its maximum effect and help prevent your hayfever symptoms from occurring.

**Directions for use:**
- Use only in the nose.
- Shake gently before use.
- Prime by pumping 10 times before initial use, or 2 times if unused for 14 days or more, until a fine mist is produced.

**Adults aged 18 and over:**
2 sprays in each nostril once a day.
Do not use more than 4 sprays a day.
Once your symptoms improve, try reducing to 1 spray in each nostril once a day; this may be sufficient to maintain relief.

**Do not use:**
- Continuously for more than 3 months without consulting your doctor.
- In children under 18 years of age.
- If you are pregnant or breastfeeding without talking to your doctor first.

**Consult your doctor:**
- If you are having trouble controlling your symptoms.
- If your symptoms have not improved after using Nasonex Allergy Control for 14 days.

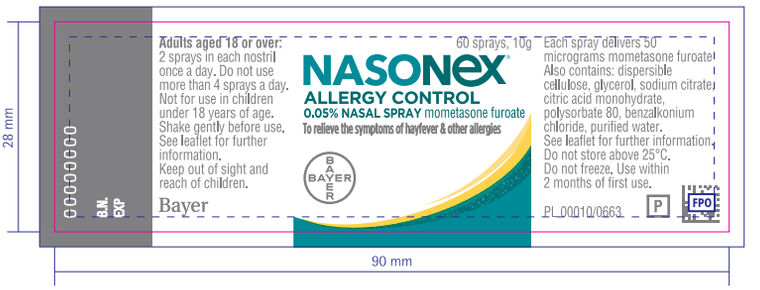
**Keep out of sight and reach of children.**

**Each spray** delivers 60 micrograms mometasone furoate
**Also contains:** dispersible cellulose, glycerol, sodium citrate, citric acid monohydrate, polysorbate 80, benzalkonium chloride, purified water.
See leaflet for further information.
**MA Holder:**
Bayer plc, Consumer Care Division, Newbury, Berkshire, RG14 1JA, U.K.
PL 00010/0663

Bayer

FPO
0 000000 000000

B.N.
EXP




Colours

| PANTONE 122 C | PANTONE 321 C | PANTONE 323 C | 323 C Tone |
|---|---|---|---|
| 1 FLX | 2 FLX | 3 FLX | 4 FLX |

| PANTONE Cool Gray 10 C | Varnish |
|---|---|
| 5 FLX | 6 FLX |

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

NASONEX Allergy Control 0.05% Nasal Spray

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

0.05% mometasone furoate (as the monohydrate). Each 100 mg actuation contains 50 micrograms of mometasone furoate.

Excipient with known effect:
This medicinal product contains 0.02 mg of benzalkonium chloride per actuation.
For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Nasal Spray, suspension.
White to off-white opaque suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

NASONEX Nasal Spray is indicated for use in adults to treat the symptoms of seasonal or perennial allergic rhinitis.

### 4.2 Posology and method of administration

After initial priming of the NASONEX Nasal Spray pump, each actuation delivers approximately 100 mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50 micrograms mometasone furoate.

**Posology**

Seasonal or Perennial Allergic Rhinitis
Adults aged 18 years and over (including older patients): The usual recommended dose is two actuations (50 micrograms/actuation) in each nostril once daily (total dose 200 micrograms). Once symptoms are controlled, dose reduction to one actuation in each nostril (total dose 100 micrograms) may be effective for maintenance. Dose reduction is recommended following control of symptoms.

Children under 18 years of age: Should not be used by children and adolescents under 18 years of age.

NASONEX Nasal Spray demonstrated a clinically significant onset of action within 12 hours after the first dose in some patients with seasonal allergic rhinitis; however, full benefit of treatment may not be achieved in the first 48 hours. Therefore, the patient should continue regular use to achieve full therapeutic benefit.

Treatment with NASONEX Nasal Spray may need to be initiated some days before the expected start of the pollen season in patients who have a history of moderate to severe symptoms of seasonal allergic rhinitis.

**Method of administration**

Prior to administration of the first dose, shake container well and actuate the pump 10 times (until a uniform spray is obtained). If the pump is not used for 14 days or longer, reprime the pump with 2 actuations until a uniform spray is observed, before next use.

Shake container well before each use. The bottle should be discarded after the labelled number of actuations or within 2 months of first use.

If symptoms have not improved after 14 days medical advice must be sought.

## 4.3 Contraindications

Hypersensitivity to the active substance, mometasone furoate, or to any of the excipients listed in section 6.1.

NASONEX Nasal Spray should not be used in the presence of untreated localised infection involving the nasal mucosa, such as herpes simplex.

Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal surgery or trauma should not use a nasal corticosteroid until healing has occurred.

## 4.4 Special warnings and precautions for use

Treatment should be stopped or the advice of a doctor sought if an improvement is not seen within 14 days. Advice of a doctor or pharmacist should also be sought if symptoms have improved but are not adequately controlled. This medicines should not be used continuously for more than 3 months without consulting a doctor.

Immunosuppression
NASONEX Nasal Spray should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, or systemic viral infections.

Patients receiving corticosteroids who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (e.g., chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs.

Local Nasal Effects
Following 12 months of treatment with NASONEX Nasal Spray in a study of patients with perennial rhinitis, there was no evidence of atrophy of the nasal mucosa; also, mometasone furoate tended to reverse the nasal mucosa closer to a normal histologic phenotype. Nevertheless, patients using NASONEX Nasal Spray over several months or longer should be examined periodically for possible changes in the nasal mucosa. If localised fungal infection of the nose or pharynx develops, discontinuance of NASONEX Nasal Spray therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing NASONEX Nasal Spray.

Nasonex is not recommended in case of nasal septum perforation (see section 4.8).

In clinical studies, epistaxis occurred at a higher incidence compared to placebo. Epistaxis was generally self-limiting and mild in severity (see section 4.8).

NASONEX Nasal Spray contains benzalkonium chloride which may cause nasal irritation.

Systemic Effects of Corticosteroids
Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects

may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children).

Following the use of intranasal corticosteroids, instances of increased intraocular pressure have been reported (see section 4.8).

Patients who are transferred from long-term administration of systemically active corticosteroids to NASONEX Nasal Spray require careful attention. Systemic corticosteroid withdrawal in such patients may result in adrenal insufficiency for a number of months until recovery of HPA axis function. If these patients exhibit signs and symptoms of adrenal insufficiency or symptoms of withdrawal (e.g., joint and/or muscular pain, lassitude, and depression initially) despite relief from nasal symptoms, systemic corticosteroid administration should be resumed and other modes of therapy and appropriate measures instituted. Such transfer may also unmask pre-existing allergic conditions, such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.

Treatment with higher than recommended doses 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.

Non-nasal Symptoms
Although NASONEX Nasal Spray will control the nasal symptoms in most patients, the concomitant use of appropriate additional therapy may provide additional relief of other symptoms, particularly ocular symptoms.

## 4.5 Interactions with other medicaments and other forms of interaction

(See 4.4 Special warnings and special precautions for use with systemic corticosteroids)

A clinical interaction study was conducted with loratadine. No interactions were observed.

## 4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of mometasone furoate in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). As with other nasal corticosteroid preparations, NASONEX Nasal Spray should not be used in pregnancy unless the potential benefit to the mother justifies any potential risk to the mother, foetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

Lactation
It is unknown whether mometasone furoate is excreted in human milk. As with other nasal corticosteroid preparations, a decision must be made whether to discontinue breast-feeding or to discontinue/abstain from NASONEX Nasal Spray therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
There are no clinical data concerning the effect of mometasone furoate on fertility. Animal studies have shown reproductive toxicity, but no effects on fertility (see section 5.3).

The leaflet and label will include a warning that medical opinion should be sought, before using this medicine, in the case of pregnancy and breastfeeding.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

Summary of the safety profile

Epistaxis was generally self-limiting and mild in severity, and occurred at a higher incidence compared to placebo (5%), but at a comparable or lower incidence when compared to the active control nasal corticosteroids studied (up to 15%) as reported in clinical studies for allergic rhinitis. The incidence of all other adverse events was comparable with that of placebo.

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

Tabulated list of adverse reactions

Treatment related adverse reactions (≥1%) reported in clinical trials in patients with allergic rhinitis or nasal polyposis and post-marketing regardless of indication are presented in Table 1. Adverse reactions are listed according to MedDRA primary system organ class. Within each system organ class, adverse reactions are ranked by frequency. Frequencies were defined as follows: Very common ( ≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100). The frequency of post-marketing adverse events are considered as "not known (cannot be estimated from the available data)".

**Table 1: Treatment-related adverse reactions reported by system organ class and frequency**

| | Very common | Common | Not known |
|---|---|---|---|
| Infections and infestations | | Pharyngitis<br>Upper respiratory tract infection† | |
| Immune system disorders | | | Hypersensitivity including anaphylactic reactions, angioedema, bronchospasm, and dyspnoea |
| Nervous system disorders | | Headache | |
| Eye disorders | | | Glaucoma<br>Increased intraocular pressure<br>Cataracts |
| Respiratory, thoracic and mediastinal disorders | Epistaxis* | Epistaxis<br>Nasal burning<br>Nasal irritation<br>Nasal ulceration | Nasal septum perforation |
| Gastrointestinal disorders | | Throat irritation* | Disturbances of taste and smell |

*recorded for twice daily dosing for nasal polyposis

†recorded at uncommon frequency for twice daily dosing for nasal polyposis

*Paediatric population*

In the paediatric population, the incidence of recorded adverse events in clinical studies, e.g., epistaxis (6%), headache (3%), nasal irritation (2%) and sneezing (2%) was comparable to placebo.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

### 4.9 Overdose

Symptoms
Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.

Management
Because the systemic bioavailability of NASONEX Nasal Spray is <1%, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Decongestants and Other Nasal Preparations for Topical Use-Corticosteroids, ATC code: R01A D09

Mechanism of action
Mometasone furoate is a topical glucocorticosteroid with local anti-inflammatory properties at doses that are not systemically active.

It is likely that much of the mechanism for the anti-allergic and anti-inflammatory effects of mometasone furoate lies in its ability to inhibit the release of mediators of allergic reactions. Mometasone furoate significantly inhibits the release of leukotrienes from leucocytes of allergic patients. In cell culture, mometasone furoate demonstrated high potency in inhibition of synthesis and release of IL-1, IL-5, IL-6 and TNFα; it is also a potent inhibitor of leukotriene production. In addition, it is an extremely potent inhibitor of the production of the Th2 cytokines, IL-4 and IL-5, from human CD4+ T-cells.

Pharmacodynamic effects
In studies utilising nasal antigen challenge, NASONEX Nasal Spray has shown anti-inflammatory activity in both the early- and late- phase allergic responses. This has been demonstrated by decreases (vs placebo) in histamine and eosinophil activity and reductions (vs baseline) in eosinophils, neutrophils, and epithelial cell adhesion proteins.

In 28% of the patients with seasonal allergic rhinitis, NASONEX Nasal Spray demonstrated a clinically significant onset of action within 12 hours after the first dose. The median (50%) onset time of relief was 35.9 hours.

Paediatric population
In a placebo-controlled clinical trial in which paediatric patients (n=49/group) were administered NASONEX Nasal Spray 100 micrograms daily for one year, no reduction in growth velocity was observed.

There are limited data available on the safety and efficacy of NASONEX Nasal Spray in the paediatric population aged 3 to 5 years, and an appropriate dosage range cannot be established. In a study involving 48 children aged 3 to 5 years treated with intranasal mometasone furoate 50, 100 or 200 μg/day for 14 days, there was no significant differences from placebo in the mean change in plasma cortisol level in response to the tetracosactrin stimulation test.

### 5.2 Pharmacokinetic properties

Absorption
Mometasone furoate, administered as an aqueous nasal spray, has a systemic bioavailability of <1% in plasma, using a sensitive assay with a lower quantitation limit of 0.25 pg/ml.

Distribution
Not applicable as mometasone is poorly absorbed via the nasal route.

Biotransformation
The small amount that may be swallowed and absorbed undergoes extensive first-pass hepatic metabolism.

Elimination
Absorbed mometasone furoate is extensively metabolized and the metabolites are excretedin urine and bile.

### 5.3 Preclinical safety data

No toxicological effects unique to mometasone furoate exposure were demonstrated. All observed effects are typical of this class of compounds and are related to exaggerated pharmacologic effects of glucocorticoids.

Preclinical studies demonstrate that mometasone furoate is devoid of androgenic, antiandrogenic, estrogenic or antiestrogenic activity but, like other glucocorticoids, it exhibits some antiuterotrophic activity and delays vaginal opening in animal models at high oral doses of 56 mg/kg/day and 280 mg/kg/day.

Like other glucocorticoids, mometasone furoate showed a clastogenic potential in-vitro at high concentrations. However, no mutagenic effects can be expected at therapeutically relevant doses.
In studies of reproductive function, subcutaneous mometasone furoate, at 15 micrograms/kg prolonged gestation and prolonged and difficult labour occurred with a reduction in offspring survival and body weight or body weight gain. There was no effect on fertility.
Like other glucocorticoids, mometasone furoate is a teratogen in rodents and rabbits. Effects noted were umbilical hernia in rats, cleft palate in mice and gallbladder agenesis, umbilical hernia, and flexed front paws in rabbits. There were also reductions in maternal body weight gains, effects on foetal growth (lower foetal body weight and/or delayed ossification) in rats, rabbits and mice, and reduced offspring survival in mice.

The carcinogenicity potential of inhaled mometasone furoate (aerosol with CFC propellant and surfactant) at concentrations of 0.25 to 2.0 micrograms/l was investigated in 24-month studies in mice and rats. Typical glucocorticoid-related effects, including several non-neoplastic lesions, were observed. No statistically significant dose-response relationship was detected for any of the tumour types.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Dispersable cellulose (microcrystalline cellulose and carmellose sodium)
Glycerol
Sodium citrate
Citric acid monohydrate
Polysorbate 80
Benzalkonium chloride,
Purified water

### 6.2 Incompatibilities

Not applicable

### 6.3 Shelf life

2 years

Use within 2 months of first use.

### 6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

### 6.5 Nature and contents of container

NASONEX Nasal Spray is contained in a white, high density polyethylene bottle, that contains 10 g (60 actuations) or 18 g (140 actuations) of product formulation, supplied with a metered dose, manual polypropylene spray pump actuator.

Pack sizes: 10g, 1 bottle
18g, 1 bottle

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Bayer plc
Bayer House
Strawberry Hill
Newbury, Berkshire
RG14 1JA

Trading as Bayer plc, Consumer Care Division

## 8. MARKETING AUTHORISATION NUMBER

PL 00010/0663

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

## 10. DATE OF REVISION OF THE TEXT

[To be completed nationally]