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# Questions and answers on Nasonex and associated names (mometasone furoate, 50 microgram, nasal spray)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 20 November 2014, the European Medicines Agency completed a review of Nasonex and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Nasonex and associated names in the European Union (EU).

## What is Nasonex?

Nasonex is an anti-inflammatory medicine that is used in adults and children from three years of age to treat the symptoms of seasonal allergic or perennial rhinitis (inflammation of the nasal passages caused by occasional or long-term allergy). In addition, it is used in adults to treat nasal polyps (growths in the lining of the nose).

Nasonex contains the active substance mometasone furoate. It is available as a nasal spray. Nasonex and associated names have been authorised in EU Member States through national procedures since 1997.

Nasonex and associated names are currently marketed in the following Member States of the EU: Austria, Belgium, Bulgaria, Croatia, Cyprus[1], Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom, as well as in Iceland and Norway.

The company that markets these medicines is Merck Sharp & Dohme.

## Why was Nasonex reviewed?

As Nasonex has been authorised in the EU via national procedures, this has led to divergences across Member States in the way the medicine can be used, as seen in differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

[1] Nasonex is marketed in Cyprus under Art.126a of Directive 27/2004 EC, which allows a country to place a product in the market for justified public health reasons for a limited number of years.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
**Send a question via our website** www.ema.europa.eu/contact

In view of this, on 17 September 2013 the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Nasonex in the EU.

## What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets for Nasonex should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

After reviewing the available data supporting the medicine's use, the CHMP agreed that Nasonex can be used for the following:

- Treatment of symptoms of seasonal allergic or perennial rhinitis in adults and in children aged three and above.
- Treatment of nasal polyps in adults (aged 18 years and older).

The Committee also agreed that Nasonex should no longer be recommended to treat acute sinusitis, which was authorised in some Member States, because the available data to support this use were considered limited.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised recommendations on the doses.

4.3 Contraindications

The CHMP agreed to that Nasonex must not be used in:

- Patients with known hypersensitivity (allergy) to mometasone furoate or to any other ingredients.
- Patients who have an untreated and localised infection, such as herpes, affecting the inside of the nose.
- Patients who have recently undergone nose surgery or who have a wound in the nose, because Nasonex can affect wound healing.

Other changes

The CHMP also harmonised other sections of the SmPC, including sections 4.4 (special warnings and precautions for use), 4.6 (fertility, pregnancy and lactation), 4.8 (side effects) and 5.1 (pharmacodynamic properties). The labelling and package leaflet were also revised in line with the changes to the SmPC.

The amended information to doctors and patients is available here.

The European Commission issued an EU-wide legally binding decision to implement these changes on 19 January 2015.