

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

NASONEX 50 micrograms/actuation Nasal Spray, Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Mometasone furoate (as the monohydrate) 50 micrograms/actuation

Excipient with known effect:

This medicinal product contains benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal Spray, Suspension.

Product imported from Spain, Germany, Greece, Belgium and Romania:

White to off-white opaque suspension

4 CLINICAL PARTICULARS

As per PA23198/011/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/011/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dispersible cellulose (microcrystalline cellulose & carmellose sodium)

Glycerol

Sodium citrate dihydrate

Citric acid monohydrate

Polysorbate 80

Benzalkonium chloride

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer package of the product on the market in the country of origin.

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 bottle, that contains 18 g (140 actuations) of product formulation, supplied with a metered-dose, manual spray pump actuator.
Each package contains one bottle.

6.6 Special precautions for disposal

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/146/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of last authorisation: July 2012
Last updated: June 2013
Last updated: October 2016
Last updated: July 2020

10 DATE OF REVISION OF THE TEXT

July 2023