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 and Belgium:
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, high density polyethylene bottle, that contains 18 g (140 actuations) of product formulation, supplied with a metered-dose, manual polypropylene 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

October 2021