

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 Greece

White to off-white opaque suspension.

4 CLINICAL PARTICULARS

As per PA1286/038/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/038/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

dispersible cellulose (microcrystalline cellulose and sodium carmellose)
glycerol
sodium citrate
citric acid monohydrate
polysorbate 80
benzalkonium chloride
purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product is the date shown on the bottle and outer package of the product as marketed 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.

Pack sizes: 18g, 1 bottles

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 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/173/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd September 2016

10 DATE OF REVISION OF THE TEXT

December 2016