

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 Belgium

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
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 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, plastic bottle that contains 140 actuations of product formulation, supplied with a metered-dose, manual plastic spray pump actuator and a turquoise cap.

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

Merit Pharmaceuticals Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th February 2018

10 DATE OF REVISION OF THE TEXT

September 2020