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, Greece 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

Product imported from Greece:
dispersible cellulose 65 cps (microcrystalline cellulose and carmellose sodium)
glycerol
sodium citrate
citric acid monohydrate
polysorbate 80
benzalkonium chloride
purified water

Product imported from Romania:
Dispersable cellulose (microcrystalline cellulose and sodium carmellose)
Glycerol
Sodium citrate dihydrate
Citric acid monohydrate
Polysorbate 80
Benzalkonium chloride
Purified water

Product imported from Belgium:
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 carton 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.
Pack sizes: 18g: 1 bottle

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/102/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd of May 2015

10 DATE OF REVISION OF THE TEXT

March 2025