

# 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 PA23198/011/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23198/011/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Dispersible cellulose 65 cps (microcrystalline cellulose and carmellose sodium)

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: 1bottle

#### **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: 22<sup>nd</sup> of May 2015

#### **10 DATE OF REVISION OF THE TEXT**

October 2021