

# 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.  
This medicinal product contains 0.2 mg of benzalkonium chloride per gram

*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 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special 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**