

# 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, Spain and Germany:*

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 & carmellose sodium)  
Glycerol  
Sodium citrate dihydrate  
Citric acid monohydrate  
Polysorbate 80  
Purified water  
Benzalkonium chloride

### 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.

Discard two months after first opening.

## **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 18g (140 actuations) of product formulation, supplied with a metered-dose, manual polypropylene spray pump actuator. Each package contains one bottle.

## **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**

PCO Manufacturing  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/146/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 19 August 2005

Date of last renewal: 19 August 2010

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

October 2016