

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Nasonex 50 micrograms/actuation Nasal Spray, Suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered actuation (spray) delivers 50 micrograms of mometasone furoate (as the monohydrate).  
Excipient: Benzalkonium chloride  
For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Nasal Spray, Suspension.  
*Product imported from the UK and 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

Dispersable cellulose  
Glycerol  
Sodium citrate dihydrate  
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 shall be 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**

Nasal spray in a cardboard outer. 140 actuations

## **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**

Imbat Limited  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/062/001

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

Date of first authorisation: 1st February 2008

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

February 2016