

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

NASACORT 55 micrograms/dose, nasal spray, suspension

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Bottles of NASACORT contain 16.5g of suspension (with 9.075 mg triamcinolone acetonide). One delivered dose contains 55 micrograms of triamcinolone acetonide.

Excipient(s) with known effect: benzalkonium chloride

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Nasal spray, suspension.

*Product imported from the Netherlands, Greece and the United Kingdom*

It is an unscented, thixotropic suspension of microcrystalline triamcinolone acetonide in an aqueous medium.

## 4 CLINICAL PARTICULARS

As per PA0540/011/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0540/011/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Product imported from the Netherlands and Greece*

Hydrochloric Acid or sodium hydroxide (to adjust pH)

Microcrystalline cellulose

Carmellose sodium

Polysorbate 80

Purified water

Glucose anhydrous

Benzalkonium chloride

Disodium edetate

*Product imported from the United Kingdom*

Microcrystalline cellulose and carmellose sodium (dispersible cellulose)

Polysorbate 80

Purified water

Anhydrous Glucose

Benzalkonium chloride (50% w/v solution)

Disodium edetate

Hydrochloric Acid or sodium hydroxide (for pH-adjustment)

### 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.

After first opening: 2 months.

### **6.4 Special precautions for storage**

Do not store above 25°C.

### **6.5 Nature and contents of container**

NASACORT is contained in a bottle fitted with a metered-dose spray pump unit.  
One bottle of NASACORT contains 16.5 g suspension, providing 120 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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/141/001

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

Date of first authorisation: 10 September 2004

Date of last renewal: 10 September 2009

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

July 2020