

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nasacort 55 micrograms/dose, nasal spray, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Triamcinolone acetonide.

Bottles of Nasacort contain 16.5g of suspension (with 9.075mg triamcinolone acetonide). Each actuation delivers 55 micrograms triamcinolone acetonide.

Excipient: benzalkonium chloride (15 micrograms/actuation)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, suspension.

Product imported from The Netherlands and Greece

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

- Hydrochloric Acid or sodium hydroxide (to adjust pH)
- Microcrystalline cellulose
- Carmellose sodium
- Polysorbate 80
- Purified water
- Glucose anhydrous
- Benzalkonium chloride
- Disodium edentate

6.2 Incompatibilities

None known.

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.

The shelf-life after the bottle is first opened is 2 months.

6.4 Special precautions for storage

Do not store above 25°C.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

20 ml high density polyethylene (HDPE) bottle fitted with a metered-dose spray pump unit. The bottle contains 16.5 g of suspension providing 120 doses. The bottle is contained in an outer cardboard carton.

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.

See section 4.2 Posology and Method of administration regarding instructions for use/handling.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing
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

March 2017