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

Excipient with known effect: 15 micrograms of benzalkonium chloride/delivered dose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, suspension.

Product imported from France
It is an unscented, off-white, 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

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 for the 16.5 g (120 actuation) pack.

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

One bottle of NASACORT contains 16.5 g of suspension, providing 120 actuations.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Primecrown 2010 Limited
4/5 Northolt Trading Estate
Belvue Road
Northolt
Middlesex UB5 5QS
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1633/069/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th May 2018

10 DATE OF REVISION OF THE TEXT