

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

NASACORT 55 micrograms/dose, nasal spray, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient with known effect: benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, suspension.

Product imported from 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

microcrystalline cellulose
carmellose sodium
polysorbate 80
purified water
anhydrous glucose
benzalkonium chloride
disodium edetate
hydrochloric acid or
sodium hydroxide (for pH - adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle 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 20 mL high density polyethylene (HDPE) bottle fitted with a metered-dose spray pump unit.

One bottle of Nasacort contains 16.5 g of 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

LTT Pharma Limited
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/148/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th February 2015

10 DATE OF REVISION OF THE TEXT