

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

NASACORT 55 micrograms/dose nasal spray, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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 France

Off-white, nasal spray suspension.

4 CLINICAL PARTICULARS

As per PA0540/011/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0540/011/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Microcrystalline cellulose and carmellose sodium (AVICEL CL 611)
Polysorbate 80
Benzalkonium chloride
Anhydrous glucose
Dilute hydrochloric acid
Sodium hydroxide
Purified water

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 bottle fitted with a metered-dose spray pump unit, 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

Lexon (UK) Limited
Unit 18, Oxleasow Road
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/032/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th August 2019

10 DATE OF REVISION OF THE TEXT