Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ryaltris 25 microgram/actuation + 600 microgram/actuation nasal spray, suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One delivered dose (the dose that leaves the actuator) contains mometasone furoate monohydrate equivalent to 25 microgram mometasone furoate and olopatadine hydrochloride equivalent to 600 micrograms olopatadine.

Excipient with known effect
Each actuation contains 0.02 mg benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, suspension

Product imported from France:
White, homogeneous suspension.

4 CLINICAL PARTICULARS

As per PA1543/002/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1543/002/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose (E460)
Dibasic sodium phosphate heptahydrate (E 339)
Carmellose sodium (E 466)
Sodium chloride
Benzalkonium chloride
Disodium edetate
Polysorbate 80 (E 433)
Hydrochloric acid (E 507)
Sodium hydroxide (E 524)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the bottle and outer package of the product on the market in the country of origin.

In-use shelf life (after first use): 2 months

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and contents of container

The nasal spray is contained in a white, high density polyethylene bottle supplied with a metered-dose, manual polypropylene spray pump actuator. The actuator is fitted with a HDPE purple cap.

1 bottle of 30 ml with 29 g suspension (240 actuations)

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/507/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th July 2024

10 DATE OF REVISION OF THE TEXT