

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dymista 137 micrograms / 50 micrograms per actuation, Nasal Spray Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g of suspension contains 1000 micrograms azelastine hydrochloride and 365 micrograms fluticasone propionate. One actuation (0.14 g) delivers 137 micrograms azelastine hydrochloride (= 125 micrograms azelastine) and 50 micrograms fluticasone propionate.

Excipient with known effect:

One actuation (0.14 g) delivers 0.014 mg benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, suspension.

Product imported from Greece.

White, homogeneous suspension.

4 CLINICAL PARTICULARS

As per PA2010/059/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/059/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Glycerol
Microcrystalline cellulose
Carmellose sodium
Polysorbate 80
Benzalkonium chloride
Phenylethyl alcohol
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 label and outer package of the product on the market in the country of origin. In-use shelf life (after first use): 6 months.

6.4 Special precautions for storage

Do not refrigerate or freeze.

6.5 Nature and contents of container

Amber glass bottle fitted with a spray pump, a nasal polypropylene applicator (actuator) and a dust cap, 23 g (at least 120 actuations) suspension.

1 bottle with 23 g suspension in 25 ml bottles (at least 120 actuations)

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/024/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th October 2018

10 DATE OF REVISION OF THE TEXT

February 2023