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(s) with known effect:
This medicinal product contain benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, suspension.

Product imported from *United Kingdom and Greece*.

White, homogenous 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 of this product shall be the date shown on the container 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 applicator (actuator) and a dust cap, containing 23 g (at least 120 actuations) suspension.
Pack size: 1 bottle with 23 g suspension in 25 ml bottle (at least 120 actuations).

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Merit Pharmaceuticals Limited
Unit C4/C3
Metropoint Business Park
Kettles Lane
Swords
Co Dublin
K67 RH92
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th February 2018

10 DATE OF REVISION OF THE TEXT

May 2023