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 (0.14g) delivers 137 micrograms azelastine hydrochloride (= 125 micrograms azelastine) and 50 micrograms fluticasone propionate.

Excipient(s) with known effect:
Contains benzalkonium chloride.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal Spray, Suspension.

Product imported from the UK, Greece, France and Czech Republic:
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 of this product is 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

Glass bottle fitted with a spray pump, a nasal applicator (actuator) and a dust cap, containing the suspension.
Pack size: 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/422/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd December 2016

10 DATE OF REVISION OF THE TEXT

December 2021