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.
Each actuation (0.14 g) delivers 137 micrograms azelastine hydrochloride (equivalent to 125 micrograms azelastine) and 50 micrograms fluticasone propionate.

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 the UK and France
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 is the date shown on the bottle and outer carton of the product as marketed 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

Cardboard outer carton containing an amber coloured glass bottle fitted with a spray pump, applicator and a protective cap.

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/151/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27th October 2017

10 DATE OF REVISION OF THE TEXT

October 2020