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 the United Kingdom.

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 solution
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 onthe market in the country oforigin.
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 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 2021