

# 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 PA1332/045/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1332/045/001

## 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  
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Block 4  
Port Tunnel Business Park  
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#### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/024/001

#### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 19<sup>th</sup> October 2018

#### **10 DATE OF REVISION OF THE TEXT**

October 2021