

# 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 Greece, France and Czech Republic:*

White homogeneous suspension

## 4 CLINICAL PARTICULARS

As per PA23355/010/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23355/010/001

## 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: 23<sup>rd</sup> December 2016

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

September 2023