

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Reminyl XL 24 mg prolonged-release capsules, hard

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 24 mg capsule, contains 24 mg galantamine (as hydrobromide).

Excipients with known effect: sucrose

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release capsule, hard

*Product imported from Italy and Greece:*

Caramel opaque, size 1 hard capsules with the inscription "G24", containing white to off-white pellets.

## 4 CLINICAL PARTICULARS

As per PA23211/003/004

## 5 PHARMACOLOGICAL PROPERTIES

As per PA23211/003/004

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Prolonged-release pellets*

Diethyl phthalate

Ethylcellulose

Hypromellose

Macrogol 400

Maize starch

Sucrose

*Capsules*

Gelatin

Titanium dioxide (E171)

Red ferric oxide (E172)

Yellow ferric oxide (E172)

*Imprinting ink*

Iron oxide black (E172)

Shellac

Propylene glycol

### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf life**

The shelf life expiry date of this product shall be the date shown on the container and outer packaging of the product on the market in the country of origin

### **6.4 Special precautions for storage**

Do not store above 30°C.

### **6.5 Nature and contents of container**

Carton containing 4 blister strips (7 capsules per strip)

Pack size: 28 capsules

### **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/166/003

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

Date of first authorisation: 31st May 2013

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

May 2022