

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Reminyl XL 24 mg prolonged-release capsules

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipients with known effect: sucrose  
For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Prolonged-release capsule, hard  
*Product imported from Italy:*  
Caramel opaque, size 1 hard capsules with the inscription "G24", containing white to off-white pellets.

### 4 CLINICAL PARTICULARS

As per PA0535/006/007

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0535/006/007

### 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 package 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**

28 prolonged-release hard capsules (PVC-PE-PVDC/Aluminium blister).

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

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

LTT Pharma Limited  
Unit 18, Oxleasow Road  
East Moons Moat  
Redditch  
Worcestershire  
B98 0RE  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/113/003

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

Date of first authorisation: 23<sup>rd</sup> January 2015

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

January 2018