Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Reminyl XL 16 mg prolonged-release capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 16 mg capsule, contains 16 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 Greece:
Pink opaque, size 2 hard capsules with the inscription “G16”, containing white to off-white pellets.

4 CLINICAL PARTICULARS

As per PA0535/006/006

5 PHARMACOLOGICAL PROPERTIES

As per PA0535/006/006

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)
The 16 mg capsules also contains iron oxide red (E172)

Imprinting ink
Iron oxide black (E172)
Shellac
Propylene glycol (E1520)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the blister strip and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 30ºC.

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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/166/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th June 2017

10 DATE OF REVISION OF THE TEXT