Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

REMINYL XL 16 mg prolonged-release capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 16 mg capsule contains 16 mg galantamine (as hydrobromide).

Excipient 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

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 granules
Diethyl phthalate
Ethylcellulose
Hypromellose
Macrogol 400
Maize starch
Sucrose

Capsule shell
Gelatin
Titanium dioxide (E171)
Red ferric oxide (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 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 30ºC.

6.5 Nature and contents of container

28 prolonged release capsules, hard (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

PPA1562/113/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th November 2014

10 DATE OF REVISION OF THE TEXT

January 2018