Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Reminyl XL 8mg Prolonged-release Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 8 mg capsule contains 8 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

Product imported from Spain
White opaque, size 4 hard capsules with the inscription “G8” containing white to off-white pellets.

4 CLINICAL PARTICULARS

As per PA0535/006/005

5 PHARMACOLOGICAL PROPERTIES

As per PA0535/006/005

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)

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the blister 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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

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

PPA1562/113/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th May 2014

10 DATE OF REVISION OF THE TEXT

April 2016