Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Reminyl XL 16 mg prolonged-release capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard prolonged-release capsule contains 16 mg galantamine (as hydrobromide).
Excipient with known effect
Sucrose
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard prolonged-release capsule
Product imported from Greece
Pink opaque hard capsule with the inscription 'G16'

4 CLINICAL PARTICULARS

As per PA1575/003/006

5 PHARMACOLOGICAL PROPERTIES

As per PA1575/003/006

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Diethyl phthalate
Ethylcellulose
Hypromellose
Macrogol 400
Maize starch
Sucrose
Gelatin
Titanium dioxide (E171)
Iron oxide red (E172)
Shellac
Iron oxide black (E172)
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 30 °C.

6.5 Nature and contents of container

Blisters of 28 hard prolonged-release capsules

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.
Joop Geesinkweg 901
1114 AB Amsterdam-Duivendrecht
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th January 2019

10 DATE OF REVISION OF THE TEXT