Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Reminyl XL 8 mg prolonged-release capsules, hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 8 mg capsule contains galantamine (ashydrobromide)
Excipient 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 and Greece
White opaque, size 4 hard capsules with the inscription "G8" containing white to off-white pellets

4 CLINICAL PARTICULARS

As per PA23211/003/002

5 PHARMACOLOGICAL PROPERTIES

As per PA23211/003/002

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 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

Carton containing 4 blister strips (7 capsules per strip).
Pack size: 28 capsules

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

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/166/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th September 2009

10 DATE OF REVISION OF THE TEXT

April 2022