

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

REMINYL 4 mg/ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml oral solution contains 4 mg galantamine (as hydrobromide).

Excipients with known effect

Methyl Parahydroxybenzoate

Propyl Parahydroxybenzoate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

Product imported from Romania

Clear and colourless oral solution

4 CLINICAL PARTICULARS

As per PA23211/003/003

5 PHARMACOLOGICAL PROPERTIES

As per PA23211/003/003

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)

Propyl Parahydroxybenzoate (E216)

Sodium Saccharin

Sodium Hydroxide

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

After first opening: 3 months.

6.4 Special precautions for storage

Do not store above 25 °C.

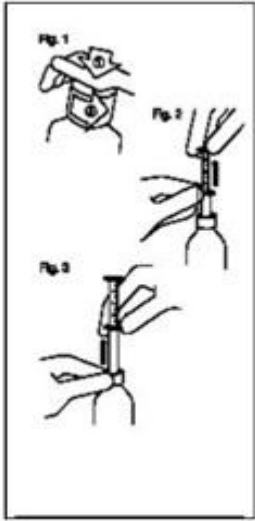
Store in the original package.

Do not freeze.

6.5 Nature and contents of container

The oral solution is packaged in a 100 ml amber glass bottle with a child-resistant closure and a pipette, calibrated in millilitres. The pipette has a minimum volume of 0.5 ml and a maximum volume of 4 ml.

6.6 Special precautions for disposal and other handling



To open the bottle and use the pipette:

Fig. 1: The bottle comes with a child-resistant cap, and should be opened as follows:

- Push the plastic screw cap down while turning it counter clockwise.
- Remove the unscrewed cap.

Fig. 2: Insert the pipette into the bottle.

While holding the bottom ring, pull the top ring up to the mark corresponding to the number of millilitres you need to give.

Fig. 3: Holding the bottom ring, remove the entire pipette from the bottle.

Empty the pipette into any non-alcoholic drink by sliding the upper ring down and drink it immediately.

Close the bottle.

Rinse the pipette with some water.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.

Joop Geesinkweg 901

1114 AB Amsterdam-Duivendrecht

Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st December 2018

10 DATE OF REVISION OF THE TEXT

March 2023