

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Eldepryl 5 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg of selegiline hydrochloride.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

Product imported from The UK:

A white or almost white, round, convex uncoated tablet having a single scoreline on one face.

4 CLINICAL PARTICULARS

As per PA1327/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1327/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol (E421)

Maize starch

Microcrystalline cellulose

Povidone

Magnesium stearate

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.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the container tightly closed.
Store in the original container.

6.5 Nature and contents of container

White HDPE bottle with HDPE closure placed in cardboard outer carton.
Pack size: 100 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PPA0465/304/001

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/304/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd February 2013
Last updated: May 2015

10 DATE OF REVISION OF THE TEXT

November 2018