

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mestinon 60 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Tablet contains 60 mg pyridostigmine bromide.

Each Tablet contains lactose monohydrate.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Spain

White to off-white, round, biplanar, bevel-edged tablets imprinted with "V" M60 across one face and with two break marks forming a cross on the other.

The tablet can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA2010/052/001.

5 PHARMACOLOGICAL PROPERTIES

As per PA2010/052/001.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Silicic acid

Corn starch

Talc

Magnesium stearate

Potato starch

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. Store in the original package. Keep the bottle tightly closed.

6.5 Nature and contents of container

Amber glass bottles with low density polyethylene caps and desiccant containing 2 x 100 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th June 2020

10 DATE OF REVISION OF THE TEXT

October 2021