

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.

Excipient(s) with known effect: lactose monohydrate.

For the full list of 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
Maize Starch
Colloidal Hydrated Silica
Talc
Magnesium stearate
Potato starch

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of 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 100 tablets. Each pack of 200 tablets contains 2 bottles of 100 tablets.

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

PPA0465/492/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th January 2022

10 DATE OF REVISION OF THE TEXT

January 2022