

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mestinon 60mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Tablet contains 60.0mg pyridostigmine bromide.
Each Tablet contains lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from the UK
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 tablets can be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA1332/034/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1332/034/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal hydrated silica
maize starch
lactose monohydrate
talc
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. Store in the original package. Keep the bottle tightly closed.

6.5 Nature and contents of container

Amber glass bottles with a desiccant enclosed, containing 200 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

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/166/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th August 2015

10 DATE OF REVISION OF THE TEXT

December 2016