Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Midon 2.5 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5 mg Midodrine hydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Hungary
Round, white, biplanar tablets with bevelled edge. Scored on one side with 'GU' above and '2.5' below the score.
The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA2239/016/001

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/016/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Talc
Colloidal anhydrous silica
Microcrystalline cellulose
Maize 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 blister 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.

6.5 Nature and contents of container

Blister packs of 100 tablets. The push-through blister comprises aluminium foil faced with PVDC, with vinyl backing also faced with PVDC.

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

Lexon Pharmaceuticals (Ireland) Limited
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Harcourt Centre
Harcourt Road
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/013/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th August 2020

10 DATE OF REVISION OF THE TEXT

November 2022