Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Midon 5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg midodrine hydrochloride.
Also contains the colourant E110 (sunset yellow FCF (E110)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Czech Republic

Orange, round, biplanar tablets with bevelled edge. Scored on one side with marking 'GU' above and '5.0' below the score. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA2239/016/002

5 PHARMACOLOGICAL PROPERTIES

As per PA2239/016/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
talc
colloidal anhydrous silica
microcrystalline cellulose
maize starch
sunset yellow (E110)

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 25ºC. Store in the original package in order to protect from light.

6.5 Nature and contents of container

Blister packs of 100 tablets. PVC/PVDC-Al blister in cardboard box.

6.6 Special precautions for disposal and other handling

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

PPA23176/013/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th August 2017

10 DATE OF REVISION OF THE TEXT

November 2022