Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Midon 5 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg midodrine hydrochloride.

Also contains the colourant E110 (Sunset Yellow FCF-Lake)

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 scoreline 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

Colloidal anhydrous silica
Microcrystalline cellulose
Maize starch
Talc
Sunset yellow FCF – Lake (E 110)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of 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. 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/160/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th August 2021

10 DATE OF REVISION OF THE TEXT

March 2023