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.

Excipient(s) with known effect:
Sunset Yellow FCF-Lake (E110)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Slovakia, Bulgaria and 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 (E110)
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25 ºC.

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

6.5 Nature and contents of container

Product imported from Slovakia
Blisters of 50 tablets

Product imported from Bulgaria and Czech Republic
Blisters 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

PPA0465/276/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th September 2011

10 DATE OF REVISION OF THE TEXT

February 2024