

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 Germany:

Round, white, biplanar tablets with bevelled edge. Scored on one side with 'GU' above and '2.5' below the score.

Product imported from Italy

Round, white, tablets. Scored on one side with ‘Gutron’ and a star symbol on the other side.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

As per PA1547/006/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1547/006/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from Germany:

- Magnesium stearate
- Talc
- Colloidal anhydrous silica
- Microcrystalline cellulose
- Maize starch

Product imported from Italy:

- Magnesium stearate
- Talc
- Colloidal anhydrous silica
- Microcrystalline cellulose
- Starch

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 25°C.

Store in the original package to protect from moisture and light.

6.5 Nature and contents of container

Product imported from Germany:

10 blisters of 10 tablets – pack size 100 tablets. The push-through blister comprises aluminium foil faced with PVDC, with vinyl backing also faced with PVDC

Product imported from Italy:

6 blisters of 15 tablets – pack size 90 tablets

Not all pack sizes may be marketed.

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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA465/276/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd July 2011

10 DATE OF REVISION OF THE TEXT

February 2016.