

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 Romania.

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

Colloidal anhydrous silica

Microcrystalline cellulose

Maize starch

Talc

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°C.

Blister packs: store in the original package.

6.5 Nature and contents of container

Blister packs of 100 tablets.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Originalis B.V.,
Joop Geesinkweg 901,
1114 AB Amsterdam-Duivendrecht,
Netherlands

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA2306/032/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of authorisation: 15th March 2024

10 DATE OF REVISION OF THE TEXT