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 Tablets

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Czech Republic:
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 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 in order to protect from light.

6.5 Nature and contents of container

PVC/PVdC-Aluminium blister pack
Each carton contains 50 or 100 tablets

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Merit Pharmaceuticals Limited
C4/C3 Metropoint Point Business Park,
Kettles Lane,
Swords,
Co Dublin,
K67 RH92,
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/024/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd September 2022

10 DATE OF REVISION OF THE TEXT