

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Mysoline 250 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 250 mg primidone.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Portugal

Round, white, biconvex tablet intagliated on one face with an "M" on either side of a scoreline and plain on the other face. The scoreline allows the tablet to be divided into equal halves.

4 CLINICAL PARTICULARS

As per PA1777/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1777/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone
Gelatin
Carmellose calcium
Magnesium stearate
Stearic acid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container 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 and moisture.
Keep the outer carton tightly closed.

6.5 Nature and contents of container

Box of 100 tablets contained in 10 PVC/aluminum blisters, each containing 10 tablets.

6.6 Special precautions for disposal

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

PPA1463/179/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th December 2021

10 DATE OF REVISION OF THE TEXT

December 2021