

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Livial 2.5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5mg of tibolone.

Excipients: also includes lactose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Greece:

White, round, flat tablets with bevelled edges, coded 'MK' above '2' on one side and 'Organon' and a star on the reverse side.

4 CLINICAL PARTICULARS

As per PA23198/021/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/021/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potato starch

Magnesium stearate

Ascorbyl palmitate

Lactose

6.2 Incompatibilities

Not applicable

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C. Keep the blister in the outer carton in order to protect from light and moisture.

6.5 Nature and contents of container

Cardboard outer containing blister strips.

Pack size: 28 or 30 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/148/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 12th June 2009

10 DATE OF REVISION OF THE TEXT

March 2022