

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Livial 2.5 mg tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5 mg of tibolone.

Excipients: also includes lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Product imported from Greece, Spain, the United Kingdom and Czech Republic:

White, circular, flat tablet 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 monohydrate

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 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.

6.5 Nature and contents of container

Blisters of 28 or 30 tablets in a carton. 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 MARKETING AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PPA0465/081/001

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/081/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 September 2001
Date of last renewal: 07 September 2006
Last updated: October 2016
Last updated: August 2018

10 DATE OF REVISION OF THE TEXT

July 2019