

## 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 monohydrate.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Tablet

*Product imported from Greece*

White, round and flat tablets with bevelled edges and a diameter of 6mm and coded "MK" above "2" on one side and "Organon" and a star on the reverse side.

### 4 CLINICAL PARTICULARS

As per PA0964/006/001

### 5 PHARMACOLOGICAL PROPERTIES

As per PA0964/006/001

### 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 for this product shall be the date shown on the bottle 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**

Each blister strip contains 30 white tablets. The blister is packed in a printed cardboard box together with the package leaflet (1 blister strips per box).

## **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**

LTT Pharma Limited  
Unit 18, Oxleasow Road  
East Moons Moat  
Redditch  
Worcestershire B98 0RE  
United Kingdom

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1562/105/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 21<sup>st</sup> February 2014

## **10 DATE OF REVISION OF THE TEXT**

December 2016