

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Logynon Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<b>Each light brown tablet contains:</b>	
Ethinylestradiol	30 micrograms
Levonorgestrel	50 micrograms

<b>Each white tablet contains:</b>	
Ethinylestradiol	40 micrograms
Levonorgestrel	75 micrograms

<b>Each ochre-coloured tablet contains:</b>	
Ethinylestradiol	30 micrograms
Levonorgestrel	125 micrograms

Excipients: Each tablet also contains lactose and sucrose.

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Coated tablet.

*Product imported from the UK*  
Each calendar-blister contains 6 light brown sugar-coated tablets, 5 white sugar-coated tablets and 10 ochre-coloured sugar-coated tablets.

## 4 CLINICAL PARTICULARS

As per PA1410/005/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1410/005/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

- Lactose
- Maize starch
- Povidone
- Magnesium stearate (E572)
- Sucrose
- Polyethylene glycol 6000
- Calcium carbonate (E170)
- Talc
- Montan glycol wax
- Glycerin (E422)

Titanium dioxide (E171)  
Ferric oxide pigment red (E172)  
Ferric oxide pigment yellow (E172)

## 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 30°C.

## 6.5 Nature and contents of container

Logynon tablets are contained in blister packs consisting of the following standard pharmaceutical packaging material: Deep drawn strips made of polyvinyl chloride film with counter-sealing foil made of aluminium with heat sealable coating.

Each calendar-blister contains 6 light brown sugar-coated tablets, 5 white sugar-coated tablets and 10 ochre-coloured sugar-coated tablets.

### Presentation

Cartons containing 1 x 21 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

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

## 8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/127/001

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

Date of first authorisation: 17th October 2014

**10 DATE OF REVISION OF THE TEXT**

March 2016