

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Logynon Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

**Each light brown tablet contains:**

Ethinylestradiol	30 micrograms
Levonorgestrel	50 micrograms

**Each white tablet contains:**

Ethinylestradiol	40 micrograms
Levonorgestrel	75 micrograms

**Each ochre-coloured tablet contains:**

Ethinylestradiol	30 micrograms
Levonorgestrel	125 micrograms

Excipients of known effect: lactose and sucrose – see leaflet for further information.

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
- talc
- sucrose
- magnesium stearate (E572)
- polyethylene glycol 6000
- calcium carbonate (E170)
- glycerin (E422)
- titanium dioxide (E171)
- ferric oxide pigment yellow (E172)

ferric oxide pigment red (E172)  
montan glycol wax

## **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 strips and outer carton of the product as marked in the country of origin.

## **6.4 Special precautions for storage**

Do not store above 30°C.

## **6.5 Nature and contents of container**

Cardboard outer containing blister strips.  
Pack size: 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**

Imbat Ltd  
Unit L2  
North Ring Business Park  
Santry  
Dublin 9

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1151/218/001

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

Date of first authorisation: 4th July 2014

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

January 2016