

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: 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
- Glycerine (E422)
- Titanium dioxide (E171)

Ferric oxide pigment yellow (E172)
Ferric oxide pigment red (E172)

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 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/072/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th October 2012

10 DATE OF REVISION OF THE TEXT

December 2015