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

Excipient(s) with known effect: Each tablet contains lactose and sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet

Product imported from the UK:
Calendar pack containing 6 round light brown sugar-coated tablets, 5 round white sugar-coated tablets and 10 round 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

Tablet core:
Lactose
Maize Starch
Povidone
Magnesium stearate (E572)
Talc

Tablet coating:
Sucrose
Polyethylene glycol 6000
Calcium carbonate (E170)
Talc
Montan glycol wax
Glycerin (E422)

Titanium dioxide (E171)
Ferric oxide pigment (red and yellow) (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 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. Each calendar-blister contains 6 light brown sugar-coated tablets, 5 white sugar-coated tablets and 10 ochre-coloured sugar-coated tablets.

Presentation
Carton 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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/311/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th July 2013

10 DATE OF REVISION OF THE TEXT

October 2019