

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 Limited
Unit L2
North Ring Business Park
Santry
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Ireland

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

October 2019