

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ovranette 150 micrograms/30 micrograms coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 150 micrograms levonorgestrel and 30 micrograms ethinylestradiol.

Excipients with known effect: Each tablet also contains lactose monohydrate and sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablets

Product imported from the United Kingdom:

Round, white sugar-coated tablets.

4 CLINICAL PARTICULARS

As per PA0822/094/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/094/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Povidone 25
Magnesium stearate
Talc
Purified water
Sucrose
Polyethylene glycol 6000
Calcium carbonate
White Wax
Wax Carnauba

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the pouch and blister strip and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Primary container: Blister strip

Secondary container: Cardboard carton. Each blister strip is packed in a pouch together with a silica gel desiccant sachet.

Presentation: Each pack contains 21 tablets.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/431/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th August 2017

10 DATE OF REVISION OF THE TEXT