Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Yasmin 0.03 mg / 3 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 0.030 mg ethinylestradiol and 3 mg drospirenone
Excipient: lactose 46 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

Product imported from The Netherlands and Romania:
Light yellow, round tablet with convex faces, one side embossed with the letters "DO" in a regular hexagon

4 CLINICAL PARTICULARS

As per PA1410/023/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/023/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose monohydrate
Maize starch
Pregelatinised maize starch
Povidone K25
Magnesium stearate

Tablet coating:
Hypromellose
Macrogol 6000
Talc
Titanium dioxide (E171)
Iron oxide pigment, 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 on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25 °C
Store in the original package

6.5 Nature and contents of container

PVC/Aluminium blister pack.
Pack size: 21 or 63 tablets
Not all pack sizes may be marketed.

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

PPA0465/326/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th January 2014

10 DATE OF REVISION OF THE TEXT

August 2016