

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Yasmin 0.03mg/3mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 0.03mg ethinylestradiol and 3mg drospirenone.

Excipient with known effect: lactose monohydrate - see leaflet for further information.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.

Product imported from The Netherlands:

Light yellow, round film-coated tablets with convex faces, embossed with the letters "DO" in a regular hexagon on one face and plain on the reverse.

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
Corn starch
Pregelatinised maize starch
Povidone K25
Magnesium stearate (E470b)

Tablet coating:

Hypromellose (E464)
Macrogol 6000
Talc (E553b)
Titanium dioxide (E171)
Yellow iron oxide (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the blister strip and outer carton of the product as marked 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

Cardboard outer carton containing blister strip.
Pack size: 21 tablets

6.6 Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/246/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 2015

10 DATE OF REVISION OF THE TEXT