Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dianette 2 mg/35 microgram coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.0mg cyproterone acetate and 0.035mg ethinylestradiol.

Excipients with known effect: lactose and sucrose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Coated Tablet

Product imported from the UK:
Beige, sugar-coated, biconvex tablets.

4 CLINICAL PARTICULARS

As per PA 1410/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA 1410/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize starch
Povidone
Talc
Magnesium stearate (E572)
Sucrose
Polyethylene glycol 6000
Calcium carbonate (E170)
Titanium dioxide (E171)
Glycerol (E422)
Montan glycol wax
Yellow ferric oxide pigment (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 and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Blister strips of 21 tablets in an outer cardboard carton.
Pack sizes: 63 tablets and 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
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/181/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th July 2012

10 DATE OF REVISION OF THE TEXT

March 2018