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 2.0 mg cyproterone acetate and 0.035 mg ethinylestradiol.

Excipients with known effect: contains lactose and sucrose

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet (tablet).

Product imported from Romania
Round, beige, sugar-coated tablets.

4 CLINICAL PARTICULARS

As per PA1410/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1410/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Product imported from UK:
Lactose
Maize starch
Povidone
Talc
Magnesium stearate (E572)
Sucrose
Macrogol 6000
Calcium carbonate (E170)
Titanium dioxide (E171)
Glycerol (E422)
Montan glycol wax
Yellow ferric oxide pigment (E172)

Product imported from Romania:
Lactose monohydrate
Maize starch
Povidone 25000
Magnesium stearate
Sucrose
Povidone 700000
Macrogol 6000
Calcium carbonate
Talc
Glycerol 85%

Titanium dioxide (E171)
Yellow ferric oxide pigment (E172)
Montan glycol wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be 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.

6.5 Nature and contents of container

Dianette tablets come in calendar blister packs of 21 and 63 (3x21) tablets.
Not all pack sizes may be marketed.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/050/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 October 1998

Date of last renewal: 16 October 2007
Date of last renewal: April 2011
Last updated: September 2014
Last updated: December 2017
Last updated June 2018

10 DATE OF REVISION OF THE TEXT

January 2024