

Summary of Product Characteristics

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

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: contains lactose and sucrose

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Coated Tablet (Tablet)

Product imported from the UK:

Beige, sugar-coated, biconvex 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

Core

Lactose

Maize starch

Povidone

Talc

Magnesium stearate (E572)

Tablet Coating

Sucrose

Povidone

Polyethylene glycol 6000

Calcium carbonate (E170)

Talc

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 strips and outer carton 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

Outer carton contains aluminium foil and PVC blister calendar pack containing 21 tablets. Each carton contains one blister calendar pack.

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

IMED Healthcare Ltd
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/050/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th September 2011

10 DATE OF REVISION OF THE TEXT

June 2015