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
Each tablet contains lactose monohydrate and sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Coated tablet (tablet).

Product imported from Romania
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 monohydrate
Maize starch
Povidone 25 000
Magnesium stearate
Talc

Tablet Coating
Sucrose
Povidone 700 000
Polyethylene glycol 6000
Calcium carbonate
Talc
Glycerol 85%
Titanium dioxide (E 171)
Ferric oxide pigment yellow (E 172)
Montanglycol wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of 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

Store below 30°C.

6.5 Nature and contents of container

Dianette tablets are contained in blister packs consisting of the following standard pharmaceutical packaging material: Deep drawn strips made of polyvinyl chloride film with counter-sealing foil made of aluminium with heat sealable coating.

Presentation:
Calendar-pack containing 21 tablets.

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

PPA1463/164/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th June 2021

10 DATE OF REVISION OF THE TEXT