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: contains lactose (as monohydrate) and sucrose

For a 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 K25
Magnesium stearate
Talc

Tablet Coating
Sucrose
Povidone K90
Macrogol 6000
Calcium carbonate
Talc
Glycerol 85%
Titanium dioxide (E 171)
Iron oxide yellow (E 172)
Montanglycol 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 blister 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

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
Harcourt Road
Dublin 2
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/033/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th August 2020

10 DATE OF REVISION OF THE TEXT

October 2021