

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Avodart 0.5 mg soft capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 0.5 mg dutasteride.

Excipient with known effect:

Each capsule contains lecithin (which may contain soya oil)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft.

Product imported from Greece.

The capsules are opaque, yellow, oblong soft gelatin capsules marked with GX CE2.

4 CLINICAL PARTICULARS

As per PA1077/104/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/104/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents:

mono- and diglycerides of caprylic/capric acid
butylhydroxytoluene (E321).

Capsule shell:

gelatin
glycerol
titanium dioxide (E171)
iron oxide yellow (E172)
triglycerides, medium chain
lecithin (may contain soya oil)

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

Do not store above 30°C.

6.5 Nature and contents of container

Blisters of opaque PVC/PVDC film containing 10 soft gelatin capsules packed into containers of 30 capsules.

6.6 Special precautions for disposal and other handling

Dutasteride is absorbed through the skin, therefore contact with leaking capsules must be avoided. If contact is made with leaking capsules, the contact area should be washed immediately with soap and water (*see section 4.4 of PA1077/104/001*).

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma
Unit 18
Oxleasow Road
East Moons Moat
Redditch
Worcestershire
B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/131/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th October 2014

10 DATE OF REVISION OF THE TEXT

June 2018