

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Avodart 0.5mg soft capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 0.5 mg dutasteride.

Excipient(s) 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 UK, France, Spain, Italy and Bulgaria:

The capsules are opaque, yellow, oblong soft gelatin capsules marked with 'GX CE2' on one side in red ink.

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).

Red printing ink containing iron oxide red (E172) as the colourant, polyvinyl acetate phthalate, propylene glycol and Macrogol 400.

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

Blister packs containing 30 soft 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).

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/211/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th June 2008

Last updated: August 2014

10 DATE OF REVISION OF THE TEXT

November 2018