

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Avodart 0.5mg Soft Capsules

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 0.5mg dutasteride

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Capsule, soft.

*Product imported from the UK and Bulgaria:*

Opaque, yellow, oblong soft gelatin capsules imprinted 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

#### 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 30°C

## **6.5 Nature and contents of container**

Over-labelled cardboard carton containing 3 blister strips.  
Pack size: 30 soft capsules.

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

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**

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

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA1463/038/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 25th June 2010.

## **10 DATE OF REVISION OF THE TEXT**

January 2015