

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Combodart 0.5 mg/ 0.4 mg hard capsules

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 0.5 mg dutasteride and 0.4 mg tamsulosin hydrochloride, (equivalent to 0.367 mg tamsulosin).

### Excipients with known effect:

Each capsule contains lecithin (which may contain soya oil) and Sunset Yellow (E110).

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Capsule, hard.

*Product imported from Spain and Czech Republic*

Oblong, hard capsules with a brown body and an orange cap imprinted with GS 7CZ in black ink.

## 4 CLINICAL PARTICULARS

As per PA1077/118/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1077/118/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Hard Capsule Shell:

Hypromellose

Carrageenan (E407)

Potassium Chloride

Titanium Dioxide (E171)

Iron Oxide Red (E172)

Sunset Yellow (E110)

Carnauba Wax

Maize Starch

Contents inside the hard capsule:

Mono-di-glycerides of caprylic/capric acid

Butylhydroxytoluene (E321)

Gelatin

Glycerol

Titanium dioxide (E171)

Iron Oxide Yellow (E172)

Triglycerides, medium chain

Lecithin (may contain soya oil)

Cellulose, Microcrystalline

Methacrylic acid - ethyl acrylate copolymer (also contains polysorbate 80 and sodium laurilsulfate)

Talc

Triethyl citrate

Black Inks (SW-9010 or SW-9008):  
Shellac  
Propylene Glycol  
Iron Oxide Black (E172)  
Potassium Hydroxide (in Black Ink SW-9008 only)

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

The shelf-life expiry date of this product is the date shown on the container 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**

HDPE bottle with closure.  
Pack size: 30 hard capsules  
Pack size: 90 hard capsules  
Not all pack sizes may be marketed.

## **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 medicinal 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**

PPA1463/068/001

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

Date of first authorisation: 19th October 2012

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

April 2022