

## 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).

Contains Sunset Yellow (E110). Each capsule contains  $\leq 0.1$  mg sunset yellow. May also contain soya (from lecithin).

For the full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Capsule, hard.

*Product imported from Poland and Bulgaria*

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

Each hard capsule contains tamsulosin hydrochloride modified release pellets and one dutasteride soft gelatin capsule.

### 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 in Dutasteride Soft Capsule:

Mono-di-glycerides of caprylic/capric acid

Butylhydroxytoluene (E321)

Soft Capsule Shell:

Gelatin

Glycerol

Titanium dioxide (E171)

Iron Oxide Yellow (E172)

Triglycerides, medium chain  
Lecithin (may contain soya oil)

Tamsulosin Pellets:

Cellulose, Microcrystalline

Methacrylic acid - ethyl acrylate copolymer 1:1 dispersion 30 per cent (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

Opaque, white high density polyethylene (HDPE) bottles with polypropylene child-resistant closures with polyethylene-faced, foil induction heat-seal liners:

30 hard capsules in 100 ml bottle

## 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

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## 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**

March 2018