

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).

Excipient(s) with known effect

Each capsule contain 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 the Czech Republic and Spain:

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

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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 bottle and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

90 hard capsules in 200 ml bottle, contained in an outer cardboard carton

30 hard capsules in 100 ml bottle, contained in an outer cardboard carton

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

PCO Manufacturing Ltd.

Unit 10, Ashbourne Business Park

Rath

Ashbourne

Co. Meath

Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/334/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th February 2014

10 DATE OF REVISION OF THE TEXT

May 2020