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 (E 110).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard.

Product imported from Lithuania.

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
Corn 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 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 for this product is 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

Opaque, white high-density polyethylene (HDPE) bottles.

30 hard capsules per bottle.

6.6 Special precautions for disposal

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

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23080/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th June 2023

10 DATE OF REVISION OF THE TEXT

February 2024