Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Proscar 5 mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg finasteride.

Excipient(s) with known effect: lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from Greece, Spain and Poland;
Blue, apple-shaped, film-coated tablets, marked 'Proscar' on one side and 'MSD 72' on the other.

4 CLINICAL PARTICULARS

As per PA23198/007/001

5 PHARMACOLOGICAL PROPERTIES

As per PA23198/007/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose (E460)
Docusate sodium
Lactose monohydrate
Magnesium stearate (E572)
Pregelatinised maize starch
Sodium starch glycolate (Type A)
Yellow iron oxide (E172)
Hydroxypropylcellulose (E463)
Indigo carmine aluminium lake (E132)
Hypromellose (E464)
Talc
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be 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. Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

Blister pack containing 14 or 28 tablets contained in an outer cardboard carton.

Not all pack sizes may be marketed.

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

Women should not handle crushed or broken 'Proscar' Tablets when they are or may potentially be pregnant (see section 4.3.'Contraindications', section 4.6.'Pregnancy and lactation', of SmPC PA23198/007/001, *Exposure to finasteride -risk to male foetus)*.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/098/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th January 2003
Last updated: September 2019

10 DATE OF REVISION OF THE TEXT

September 2022