

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Proscar 5mg Film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg of the active ingredient finasteride

Excipient: Each tablet contains lactose monohydrate

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet (tablet).

Product imported from Austria:

Blue, apple-shaped, film-coated tablets, marked 'PROSCAR' on one side and 'MSD 72' on the other.

4 CLINICAL PARTICULARS

As per PA1286/017/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1286/017/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Pregelatinised maize starch
Poly (o-carboxymethyl)-starch sodium
Docusate sodium
Magnesium stearate
Hypromellose
Hydroxypropyl cellulose
Talc
Iron oxide (E172)
Titanium dioxide (E171)
Indigo carmine aluminum lake (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the Blister 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 original package in order to protect from light.

6.5 Nature and contents of container

Opaque blisters lidded with aluminium foil in an outer carton; packs of 28 tablets.

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 4.3 'Contra-indications', 4.6 'Pregnancy and lactation', *Exposure to finasteride - risk to male foetus*).

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
Unit 18, Oxleasow Road
East Moons Moat
Redditch
Worcestershire B98 0RE
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/072/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th January 2012

10 DATE OF REVISION OF THE TEXT

November 2015