

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 of the active ingredient finasteride.

Excipient with known effect: Each tablet contains lactose monohydrate

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet (tablet).

Product imported from Poland

Blue, 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

Tablet core:

Microcrystalline cellulose

Sodium docusate

Lactose monohydrate

Magnesium stearate

Pregelatinised starch

Sodium starch glycolate type A

Yellow iron oxide (E172)

Film-Coating

Hypromellose

Indigo carmine (E132)

Hydroxypropyl cellulose

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 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 the original package in order to protect from light.

6.5 Nature and contents of container

Opaque blisters lidded with 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/127/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th November 2019

10 DATE OF REVISION OF THE TEXT

November 2021