

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Proscar 5mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5mg of the active ingredient finasteride.

Excipient: lactose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

Product imported from the UK and Spain:

Blue, apple-shaped, 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

Product Imported from the UK:

Tablet Core

Microcrystalline cellulose

Docusate sodium

Lactose

Magnesium stearate

Pregelatinised maize starch

Sodium starch glycolate type A

Yellow iron oxide (E172)

Film-Coating

Hyprolose

Indigo carmine aluminium lake (E132)

Hypromellose

Talc

Titanium dioxide (E171)

Product Imported from Spain:

Tablet Core

Microcrystalline cellulose

Docusate sodium

Lactose

Magnesium stearate
Maize starch
Sodium glycolate
Iron oxide (E172)

Film-Coating

Hydroxypropyl cellulose
Indigo carmine aluminium lake (E132)
Methylhydroxypropyl 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 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.

6.5 Nature and contents of container

Calendar blister packs in a cardboard carton containing 28 tablets.

6.6 Special precautions for disposal and other handling

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

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 19th December 2007

10 DATE OF REVISION OF THE TEXT

October 2014