

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Finasteride 5 mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated 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 the UK*

Blue, round biconvex, film-coated tablet with "F5" marking on one side and plain on other side.

## 4 CLINICAL PARTICULARS

As per PA1390/013/002

## 5 PHARMACOLOGICAL PROPERTIES

As per PA1390/013/002

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

**Tablet core:**

Lactose monohydrate,  
Cellulose microcrystalline (E460),  
Starch pregelatinised (maize)  
Lauroyl macroglycerides,  
Sodium starch glycolate (type-A),  
Magnesium stearate (E572)

**Film coating:**

Hypromellose (E464)  
Titanium dioxide (E171)  
Indigo carmine (E132)  
Macrogol 6000

### 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

This medicinal product does not require any special storage conditions.

### 6.5 Nature and contents of container

An opaque white (PVC-PVdC /Aluminium) Blister

The finasteride 5mg tablets are packed in blister packs of 28 tablets.

### 6.6 Special precautions for disposal and other handling

Women who are pregnant or may become pregnant should not handle finasteride tablets especially if crushed or broken because of the possibility of absorption of finasteride and the subsequent potential risk to a male foetus (see section 4.6).

Any unused product or waste material should be disposed of in accordance with local requirements.

## 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

PPA1562/185/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16<sup>th</sup> September 2016

## 10 DATE OF REVISION OF THE TEXT

May 2018