

**FINAST**

---

**1. Generic Name**

Finasteride Tablets I.P. 1 mg

**2. Qualitative and quantitative composition**

Each film coated tablet contains

Finasteride I.P.....1 mg

Colour: Indigo Carmine & Titanium Dioxide I.P.

The excipients used are Lactose, Microcrystalline Cellulose, Pregelatinised Starch, Hydroxy Propyl Cellulose, Isopropyl Alcohol, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Magnesium Stearate, Talcum, Sodium Lauryl Sulphate, Croscarmellose Sodium, Hydroxy Propyl Methyl Cellulose, Polyethylene Glycol 6000, Titanium Dioxide, Methylene Chloride, Colour Indigo Carmine Lake.

**3. Dosage form and strength**

**Dosage form:** Tablets

**Strength:** 1 mg

**4. Clinical particulars**

**4.1 Therapeutic indication**

Finast 1 mg tablets are indicated for in treatment of male pattern hair loss in men only.

**4.2 Posology and method of administration**

**Posology**

The recommended dosage is one 1mg tablet per day.

There is no evidence that a higher dose increases efficacy.

The efficacy and continuation of the treatment should continuously be assessed by the treating physician. Generally, finasteride 1 mg must be taken once daily for 3-6 months before evidence of stabilisation of hair loss can be expected. Continuous use is recommended for a sustained beneficial effect. If the treatment is stopped, the beneficial effect begins to disappear after 6 months, and has completely disappeared after 9-12 months.

**Dosage in renal insufficiency**

The dosage does not need to be adjusted in patients with renal insufficiency.

**Dosage in hepatic insufficiency**

There are no data available in patients with hepatic insufficiency.

**Paediatric population**

There is no relevant use of finasteride 1mg in the paediatric population.

## **Method of administration**

Oral use

It can be administered with or without a meal.

Crushed or broken tablets of finasteride 1 mg should not be handled by women when they are or may potentially be pregnant because of the possibility of absorption of finasteride and subsequent potential risk to a male foetus. Finasteride 1mg tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed.

The tablets should be swallowed whole and must not be divided or crushed.

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients.

Finasteride should not be used in children/adolescents.

Contraindicated in women.

Should not be taken by men who are taking finasteride 5 mg or any other 5 $\alpha$ - reductase inhibitor for benign prostatic hyperplasia or any other condition.

### **4.4 Special warnings and precautions for use**

#### **Evaluation of prostate-specific antigen**

In reported clinical studies with finasteride 1 mg in men 18 - 41 years of age, the mean value of serum prostate-specific antigen (PSA) decreased from 0.7 ng/ml at baseline to 0.5 ng/ml at month 12. This decrease in serum PSA concentrations needs to be considered, if during treatment with Finasteride 1mg film-coated tablets, a patient requires a PSA assay. In this case it should be considered to double PSA value before making a comparison with the results from untreated men.

Patients who are planning to father a child should consider to stop treatment.

#### *Hepatic impairment*

The effect of hepatic insufficiency on the pharmacokinetics of finasteride has not been studied.

#### *Breast cancer*

Breast cancer has been reported in men taking Finasteride 1 mg in the post-marketing period.

Physicians should instruct their patients to promptly report any changes in their breast tissue such as lumps, pain, gynaecomastia or nipple discharge.

#### *Mood alterations and depression*

Mood alterations including depressed mood, depression and, less frequently, suicidal ideation have been reported in patients treated with finasteride 1 mg. Patients should be monitored for psychiatric symptoms and if these occur, treatment with finasteride should be discontinued and the patient advised to seek medical advice.

#### *Paediatric population*

Finasteride should not be used in children. There are no data demonstrating efficacy or safety of finasteride in children under the age of 18.

## 4.5 Drugs interactions

No drug interactions of clinical importance have been identified. Finasteride is metabolised primarily via, but does not affect, the P450-3A4 system. Although the risk of finasteride to affect the pharmacokinetics of other drugs is estimated to be small, it is probable that inhibitors and inducers of cytochrome P450 3A4 will affect the plasma concentration of finasteride. However, based on established safety margins, any increase due to concomitant use of such inhibitors is unlikely to be of clinical significance. Compounds which have been tested in man have included antipyrine, digoxin, glibenclamide, propranolol, theophylline and warfarin and no interactions were found.

Due to lacking data for the concomitant use of finasteride and topical minoxidil in male pattern hair loss the combination is not recommended.

Interaction studies have only been performed in adults.

## 4.6 Use in special populations

### Pregnancy

Finasteride is contraindicated in women due to the risk in pregnancy. Because of the ability of finasteride to inhibit conversion of testosterone to dihydrotestosterone (DHT) Finasteride may cause abnormalities of the external genitalia of a male foetus when administered to a pregnant woman.

### *Exposure to finasteride: risk to male foetus*

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.

Small amounts of finasteride have been recovered from the semen in subjects receiving finasteride 5 mg/day. It is not known whether a male foetus may be adversely affected if his mother is exposed to the semen of a patient being treated with finasteride. When the patient's sexual partner is or may potentially be pregnant, the patient is recommended to minimise exposure of his partner to semen (e. g. by using condoms).

### Breast-feeding

Finasteride 1 mg are not indicated for use in women. It is not known whether finasteride is excreted in human breast milk.

### Fertility

Long-term reported data on fertility in humans are lacking, and specific studies in sub fertile men have not been conducted. The male patients who were planning to father a child were initially excluded from clinical trials.

Although, reported animal studies did not show relevant negative effects on fertility, spontaneous reports of infertility and/or poor seminal quality were received post- marketing. In some of these reports, patients had other risk factors that might have contributed to infertility. Normalisation or improvement of seminal quality has been reported after discontinuation of finasteride.

## 4.7 Effects on ability to drive and use machines

Finasteride has no or negligible influence on the ability to drive and use machines.

## 4.8 Undesirable effects

The adverse reactions reported during clinical trials and/or post-marketing use are listed in

the table below.

Frequency of adverse reactions is determined as follows:

Very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $<1/10$ ); uncommon ( $\geq 1/1,000$  to  $<1/100$ ); rare ( $\geq 1/10,000$  to  $<1/1,000$ ); very rare ( $<1/10,000$ ); not known (cannot be estimated from the available data).

The frequency of adverse reactions reported during post-marketing use cannot be determined as they are derived from spontaneous reports.

<b>Immune system disorders</b>	Not known: Hypersensitivity reactions, including rash, pruritus, urticaria, and angioedema (including swelling of the lips, tongue, throat and face).
<b>Psychiatric disorders</b>	Uncommon*: Decreased libido Uncommon: Depression† Not known: Anxiety.
<b>Cardiac disorders</b>	Not known: Palpitations
<b>Hepatobiliary disorders</b>	Not known: Increased hepatic enzymes
<b>Reproductive system and breast disorders</b>	Uncommon*: Erectile dysfunction, ejaculation disorder (including decreased volume of ejaculate). Not known: Breast tenderness and enlargement (gynecomastia), testicular pain, haemospermia, infertility**

\* Incidences presented as difference from placebo in clinical studies at month 12.

† This adverse reaction was identified through reported post-marketing surveillance but the incidence in randomized controlled Phase III clinical trials (Protocols 087, 089, and 092) was not different between finasteride and placebo

Drug-related sexual undesirable effects were more common in the finasteride 1 mg-treated men than the placebo-treated men, with frequencies during the first 12 months of 3.8% vs 2.1%, respectively. The incidence of these effects decreased to 0.6% in finasteride 1 mg-treated men over the following four years. Approximately 1% of men in each treatment group discontinued due to drug related sexual adverse experiences in the first 12 months, and the incidence declined thereafter.

In addition, the following have been reported in post-marketing use: persistence of sexual dysfunction (decreased libido, erectile dysfunction after discontinuation of treatment with finasteride; male breast cancer.

### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: [http://www.torrentpharma.com/index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting).

## 4.9 Overdose

In reported clinical studies, single doses of finasteride up to 400 mg and multiple doses of finasteride up to 80 mg/day for 3 months (n = 71) did not result in dose-related undesirable effects.

No specific treatment for an overdose of Finasteride 1 mg film-coated tablets is recommended.

## 5. Pharmacological properties

### 5.1 Mechanism of action

Pharmacotherapeutic group: Other dermatologicals, ATC code: D11AX10

Finasteride is a 4-azasteroid, which inhibits human type II 5 $\alpha$ -reductase (present in the hair follicles) with a more than 100-fold selectivity compared with human type I 5 $\alpha$ -reductase, and blocks the peripheral conversion of testosterone to the androgenic dihydrotestosterone (DHT). In men with male pattern hair loss, the balding scalp contains miniaturised hair follicles and increased concentrations of DHT. Finasteride inhibits the process responsible for miniaturisation of the scalp hair follicles, which can lead to reversal of the balding process.

### 5.2 Pharmacodynamics properties

#### *Clinical efficacy and safety*

#### Reported Studies in men

The efficacy of finasteride has been demonstrated in three reported studies in 1879 men between 18 and 41 years old with mild to moderate, but not complete, hair loss on the crown and hair loss on the frontal/mid-area of the head. In these studies the hair growth was assessed on the basis of 4 different parameters, namely hair count, assessment of photographs of the head by a panel of expert dermatologists, assessment by the investigator and assessment by the patient himself.

In two reported studies in men with vertex hair loss, the treatment with finasteride was continued for 5 years; in this period, an improvement occurred compared with baseline and placebo, beginning after 3 to 6 months.

Although the improvement in hair growth compared to baseline in the men treated with finasteride was generally greatest after 2 years and then gradually decreased (the increase in hair count in a representative area of 5.1 cm<sup>2</sup> two years after the start of treatment was 88 hairs compared with 38 hairs 5 years after the start of treatment), the hair loss in the placebo group was progressively poorer in comparison to baseline (decrease of 50 hairs after 2 years and 239 hairs after five years). Thus, although the improvement in comparison to baseline did not continue further after 2 years in the men treated with finasteride, the difference between the treatment groups during the 5-year studies continued to increase. Treatment with Finasteride for 5 years resulted in stabilisation of the hair loss in 90 % of the men on the basis of photographic assessment and in 93 % on the basis of assessment by the investigator. In addition, increased hair growth was observed in 65 % of the men treated with Finasteride on the basis of hair count, in 48 % on the basis of photographic assessment, and in 77 % on the basis of assessment by the investigator. In contrast, in the placebo group a gradual hair loss over time was observed in 100 % of the men on the basis of hair count, in 75 % on the basis of photographic assessment, and in 38 % on the basis of assessment by the investigator. In addition, assessment by the patients themselves gave a significant increase in hair density, reduction in hair loss, and improvement in the appearance of the hair after 5 years of treatment with finasteride (see the table below).

Table 1: Percentage of patients with improvement, assessed on the basis of each of the 4 criteria

	Year 1 <sup>†</sup>		Year 2 <sup>††</sup>		Year 5 <sup>††</sup>	
	finasteride	placebo	finasteride	placebo	finasteride	placebo
Hair count	(N=679) 86	(N=672) 42	(N=433) 83	(N=47) 28	(N=219) 65	(N=15) 0

Photos of the head	(N=720) 48	(N=709) 7	(N=508) 66	(N=55) 7	(N=279) 48	(N=16) 6
Assessment by the investigator	(N=748) 65	(N=747) 37	(N=535) 80	(N=60) 47	(N=271) 77	(N=13) 15
Assessment by the patient himself: satisfaction with the general appearance of the hair	(N=750) 39	(N=747) 22	(N=535) 51	(N=60) 25	(N=284) 63	(N=15) 20

† Randomisation 1:1 finasteride: placebo

†† Randomisation 9:1 finasteride: placebo

In a reported study lasting 12 months in men with hair loss on the frontal/mid-area of the head, hair counts were performed in a representative area of 1 cm<sup>2</sup> (approximately 1/5 of the area on which counts were performed in the vertex studies). The hair count, corrected for an area of 5.1 cm<sup>2</sup>, increased by 49 hairs (5 %) compared with baseline, and by 59 hairs (6 %) compared with placebo. This study also showed a significant improvement in self-assessment by the patient, in assessment by the investigator, and in the scores on the basis of photos of the head by a panel of expert dermatologists.

Two reported studies of 12 and 24 weeks showed that a dose of 5 times the recommended dosage (finasteride 5 mg/day) resulted in a median decrease in the volume of the ejaculate of about 0.5 ml (-25 %) compared with placebo. This decrease was reversible after the discontinuation of treatment. In a study lasting 48 weeks, finasteride 1 mg/day resulted in a median decrease in ejaculate volume of 0.3 ml (-11 %) compared with 0.2 ml (-8 %) for placebo. No effect on the number, motility and morphology of the spermatozoa was observed. There are no longer-term data available. It was not possible to carry out clinical trials that might directly reveal a possible negative effect on fertility. However, such effects are considered extremely unlikely.

#### Clinical efficacy in women:

No efficacy was demonstrated in post-menopausal women with androgenetic alopecia who were treated with finasteride 1 mg for 12 months.

### **5.3 Pharmacokinetic properties**

#### **Absorption:**

The oral bioavailability of finasteride is approximately 80% and is not affected by food. The peak finasteride plasma concentration is reached approximately two hours after administration; the absorption is complete after six to eight hours.

#### **Distribution**

Protein binding is approximately 93%. The volume of distribution of finasteride is approximately 76 litres (44-96 l). At steady state following administration of 1 mg/day, the mean maximum finasteride plasma concentration was 9.2 ng/ml and was reached 1 to 2 hours after administration; the AUC (0-24 hours) was 53 ng x hours/ml.

Finasteride has been recovered in the cerebrospinal fluid (CSF), but the drug does not appear to concentrate preferentially there. A very small amount of finasteride has also been detected in the seminal fluid of subjects receiving the drug. From studies in rhesus monkeys it appears that this amount is not considered to constitute a risk for the growing male foetus.

#### **Biotransformation**

Finasteride is metabolised primarily via the cytochrome P450 3A4 system, but has no effect

here. Following an oral dose of <sup>14</sup>C-finasteride in man, two metabolites of the drug were identified that represent only a small fraction of the inhibitory activity of finasteride on 5 $\alpha$ -reductase.

### **Excretion**

Following an oral dose of <sup>14</sup>C-finasteride in man, approximately 39% (32-46 %) of the dose was excreted in the urine in the form of metabolites. Virtually no unchanged drug was excreted in the urine and 57 % (51-64 %) of the total dose was excreted in the faeces.

Plasma clearance is approximately 165 ml/min (70-279 ml/min).

The elimination rate of finasteride decreases somewhat with age. The mean terminal half-life is approximately 5-6 hours (3-14 hours), and in men more than 70 years of age 8 hours (6-15 hours). These findings are of no clinical significance and therefore a reduction in dosage in the elderly is not necessary.

### **Hepatic Impairment**

The effect of hepatic insufficiency on the pharmacokinetics of finasteride has not been studied.

### **Renal Impairment**

In patients with a chronic disturbance of renal function with creatinine clearance between 9 and 55 ml/min the area under the curve, the peak plasma concentrations, the half-life and the protein-binding of unchanged finasteride after a single dose of <sup>14</sup>C-finasteride were virtually identical to the values in healthy volunteers.

## **6. Nonclinical properties**

### **6.1 Animal Toxicology or Pharmacology**

#### ***Mutagenicity/carcinogenicity***

In reported genotoxicity and carcinogenicity studies no dangers for humans were revealed.

Negative effect on reproduction, including fertility

The effect on embryonal and foetal development has been studied in rats, rabbits and rhesus monkeys. In rats that were treated with 5-5000x the clinical dose, a dose-dependent occurrence of hypospadias in male foetuses was observed. In rhesus monkeys, treatment with oral doses of 2 mg/kg/day also resulted in abnormalities of the external genitalia. After intravenous doses of up to 800 ng/day in rhesus monkeys no effects on the male foetuses were observed. This represents at least 750 times the highest estimated exposure of pregnant women to finasteride from the semen of men who take 1 mg/day. In the reported study in rabbits the foetuses were not exposed to finasteride during the critical period for the development of the genitalia.

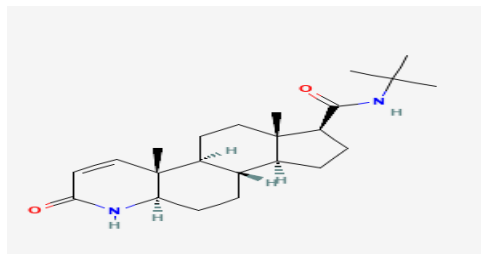
In rabbits, after treatment with 80 mg/kg/day, a dose which in other studies was shown to have a clear weight-lowering effect on the gonads, no effect on ejaculate volume, sperm count or fertility was observed. In rats that were treated for 6 and 12 weeks with 80 mg/kg/day (about 500 times the clinical dose), no effect on fertility was observed. After treatment for 24-30 weeks some reduction in fertility and a clear decrease in weight of the prostate and the seminal vesicles was observed. All these changes appeared to be reversible within 6 weeks. The reduced fertility appeared to be the result of disturbed semen plug formation, an effect that is not relevant for humans. The development of the newborns and their ability to reproduce at sexually mature age were normal. After insemination of female rats with spermatozoa from the epididymis of rats that had been treated for 36 weeks with

80 mg/kg/day, no effect on the various fertility parameters was observed.

## 7. Description

### Finasteride

Finasteride is 17 $\beta$ -(N-tert-butylcarbamoyl)-4-aza-5 $\alpha$ -androst-1-en-3-one. The molecular formula is C<sub>23</sub>H<sub>36</sub>N<sub>2</sub>O<sub>2</sub> and the molecular weight is 372.6. The chemical structure of Finasteride is:



**Finast** tablets are blue coloured, round biconvex plain on both side & film coated tablets. The excipients used are Lactose, Microcrystalline Cellulose, Pregelatinised Starch, , Hydroxy Propyl Cellulose, Isopropyl Alcohol, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Magnesium Stearate, Talcum, Sodium Lauryl Sulphate, Croscarmellose Sodium, Hydroxy Propyl Methyl Cellulose, Polyethylene Glycol 6000, Titanium Dioxide, Methylene Chloride, Colour Indigo Carmine Lake.

## 8. Pharmaceutical particulars

### 8.1 Incompatibilities

None Stated

### 8.2 Shelf-life

Do not use later than date of expiry.

### 8.3 Packaging information

Finast is available in pack of 10 Tablets

### 8.4 Storage and handing instructions

Store protected from Light & Moisture, at a temperature not exceeding 30°C.

Keep all medicines out of reach of children.

## 9. Patient Counselling Information

**Package leaflet: Information for the user**

**FINAST**



## Finasteride Tablets I.P. 1 MG

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 9.4.

### **What is in this leaflet?**

- 9.1** What FINAST is and what it is used for
- 9.2** What you need to know before you use FINAST
- 9.3** How to use FINAST
- 9.4** Possible side effects
- 9.5** How to store FINAST
- 9.6** Contents of the pack and other information

### **9.1 What FINAST is and what it is used for**

FINAST is film coated tablet, contains Finasteride 1 mg. and It is use in treatment of male pattern hair loss in men only.

Your doctor has prescribed Finasteride because you have male pattern hair loss (also known as androgenetic alopecia). Finasteride prevents further hair loss in men. Men with mild to moderate, but not complete hair loss, can benefit from using Finasteride.

Finasteride block an important enzyme (Type II 5 $\alpha$ -reductase), which is involved in the regulation of the hair follicle.

In the scalp, finasteride specifically lower the levels of DHT, a major cause of male pattern hair loss. In this way, finasteride help to reverse the balding process and prevent further hair loss.

### **9.2 What you need to know before you use FINAST Do not take**

- if you are allergic to finasteride or any of the other ingredients of this medicine.
- if you are a child or adolescent.
- if you are female (also see ‘Pregnancy and breast-feeding’). Finasteride has been found to be ineffective in the treatment of hair loss (androgenetic alopecia) in women in reported clinical studies.
- if you are already taking finasteride or any other 5 $\alpha$ -reductase inhibitor (e.g. dutasteride) for an enlargement of the prostate gland (benign prostatic hyperplasia (BPH)) or any other condition.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Finasteride: if you are planning to have a baby (father a child), as this medicine may affect male fertility or sexual activity.

### **During treatment**

This medicine may affect the results of a blood test used to detect changes in the prostate, including the development of prostate cancer. If you are due to have a blood test, remind your doctor, nurse or hospital staff that you are taking this medicine.

Finasteride has also been reported to increase the risk of changes in the chest (breasts) of men taking this medicine. You should promptly report to your doctor any changes in your breast tissue such as lumps, pain, enlargement of the breast tissue or nipple discharge as these may be signs of a serious condition, such as breast cancer.

### **Mood alterations and depression**

Mood alterations such as depressed mood, depression and, less frequently, suicidal thoughts have been reported in patients treated with finasteride. If you experience any of these symptoms stop taking this medicine and contact your doctor for further medical advice as soon as possible.

### **Children and adolescents**

Do not give this medicine to children and adolescents aged less than 18 years.

### **Other medicines and Finasteride**

Finasteride does not usually interfere with other medicines. But tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including those obtained without a prescription.

No information is available on the use of finasteride together with topical (applied to the skin) minoxidil in male pattern hair loss. The combination is not recommended.

### **Pregnancy**

Finasteride is only intended for men. If taken by a woman during pregnancy, it can affect the normal development of a male baby's sex organs. Crushed or broken tablets should not be handled by a pregnant woman because of the risk of finasteride being absorbed in the body.

Finasteride has also been found in the semen of men taking finasteride. If your sexual partner is pregnant or thinks she may be pregnant, you must use a condom to avoid exposing her to your semen, which may contain finasteride. If you have any questions, ask your doctor.

### **Fertility**

If you are planning to have a baby (father a child), talk to your doctor or pharmacist before taking finasteride, as this medicine may affect male fertility or sexual activity.

### **Breast-feeding**

Finasteride is not prescribed for women. It is not known if it can pass into breast milk.

### **Driving and using machines**

Finasteride should not affect your ability to drive or use machines.

## **9.3 How to use FINAST**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### **How much to take and when**

The amount of **FINAST** people have to take varies depending on their condition. Your doctor will tell you exactly how many tablets of **FINAST** to take.

### **How to take FINAST**

Swallow the tablets whole with some water.

### **How long to take FINAST**

Take FINAST every day for as long as your doctor tells you.

Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

### **If you take more FINAST than you should**

If you take more Finasteride than you should tell your doctor or go to your nearest hospital emergency department. Take the container and any remaining tablets with you.

### **If you forget to take FINAST**

If you forget to take Finasteride do not take a double dose to make up for a forgotten dose. Take the next dose on time.

### **If you stop taking FINAST**

If you stop taking Finasteride you are likely to lose the hair you have gained within the following 12 months.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **9.4 Possible Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of these side effects have usually been temporary with continued treatment or disappeared when treatment is stopped.

The following side effects are important and will require immediate action if you experience them.

Stop taking this medicine and talk to your doctor immediately or go to the nearest hospital emergency department if you have any of the following symptoms:

- swelling of your face, lips, tongue or throat
- difficulty swallowing
- skin rash, itching, lumps under your skin (hives)
- breathing difficulties

If you notice any of the following, talk to your doctor straight away:

lumps, pain, enlargement of the breast (chest) tissue or nipple discharge. These may be signs of a serious condition, such as breast cancer.

The following other side effects have been reported:

### **Uncommon (may affect up to 1 in 100 people):**

- decreased sexual drive
- erectile dysfunction
- problems with ejaculation, such as a decreased volume of ejaculation
- depression

### **Not known (frequency cannot be estimated from the available data):**

- pain in the testicles

- blood in semen
- fast heartbeat
- persistent difficulty having an erection after discontinuation of treatment
- infertility has been reported in men who took finasteride for a long time and had other risk

factors that may affect fertility. Normalisation or improvement of seminal quality has been reported after discontinuation of finasteride. Long-term clinical studies about the effect of finasteride on fertility in men have not been conducted.

- changes in the way your liver is working, which can be shown by a blood test
- anxiety

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: [http://www.torrentpharma.com/index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting).

### **9.5 How to store FINAST**

Store protected from Light & Moisture, at a temperature not exceeding 30°C.

Keep all medicines out of reach of children.

### **9.6 Contents of the pack and other information**

**FINAST** contain active substance Finasteride

The excipients used are Lactose, Microcrystalline Cellulose, Pregelatinised Starch, Hydroxy Propyl Cellulose, Isopropyl Alcohol, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Magnesium Stearate, Talcum, Sodium Lauryl Sulphate, Croscarmellose Sodium, Hydroxy Propyl Methyl Cellulose, Polyethylene Glycol 6000, Titanium Dioxide, Methylene Chloride, Colour Indigo Carmine Lake.

Finast is available in pack of 10 Tablets

### **10 Details of manufacturer**

M/s. Malik Lifesciences Pvt. Ltd.

Plot No. 16, Vardhman Indl. Estate,

Vill- Bahadarpur Saini, N.H. 58,

Haridwar-247 667, (Uttarakhand).

### **11 Details of permission or licence number with date**

48/UA/2014 issued on 16.12.2017

### **12 Date of revision**

NA

**MARKETED BY**



**TORRENT PHARMACEUTICALS LTD.**

**IN/FINAST 1 mg/AUG-2022/01/PI**