# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Finasteride 1 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 1 mg of finasteride.

Excipient with known effect: Each film-coated tablet contains 87.49mg of lactose monohydrate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet (tablet)

Red, round, biconvex film-coated tablets, marked with “BL1” on one side and plain on the other side.

### 4.1 Therapeutic indications

Finasteride 1 mg is indicated for treatment of the first stage of the hair loss (androgenetic alopecia) in males. Finasteride 1 mg stabilizes the process of the androgenetic alopecia in the 18- 41 year old males. Its effectiveness in temporary recession nor in the loss of hair has not been determined.

Finasteride 1mg is not indicated for use in women or children and adolescents.

### 4.2 Posology and method of administration

*Posology*

The recommended dosage is one 1 mg tablet daily. The tablet should be swallowed whole and must not be divided or crushed (See section 6.6). The film-coated tablets can either be taken on an empty stomach or with a meal.

There is no evidence that an increase in dosage will result in increased efficacy.

Efficacy and duration of treatment should continuously be assessed by the treating physician. Generally, three to six months of once daily treatment are required before evidence of stabilisation of hair loss can be expected. Continuous use is recommended to sustain benefit. If treatment is stopped, the beneficial effects begin to reverse by six months and return to baseline by 9 to 12 months.

*Dosage in renal insufficiency*

No dosage adjustment is required in patients with renal insufficiency.

*Dosage in hepatic insufficiency*
There are no data available in patients with hepatic insufficiency

No data are available on the concomitant use of finasteride and topical minoxidil in male pattern hair loss.

*Method of administration*

For oral use

Crushed or broken tablets of Finasteride should not be handled by women when they are or may potentially be pregnant because of the possibility of absorption of finasteride and the subsequent potential risk to a male foetus (see section 4.6 Fertility, pregnancy and lactation). Finasteride tablets are coated to prevent contact with the active ingredient during normal handling, provided that the tablets are not broken or crushed.

## 4.3 Contraindications

- Hypersensitivity to active substance(s) or to any of the excipients listed in section 6.1

- Contraindicated in women: see sections 4.6 ‘Fertility, pregnancy and lactation’ and 5.1 ‘Pharmacodynamic properties’.

- This medicine is not indicated for use in women or children and adolescents.
- Finasteride 1mg should not be taken by men who are taking Finasteride 5mg or any other 5α reductase inhibitor for benign prostatic hyperplasia or any other condition.

## 4.4 Special warnings and precautions for use

*Paediatric population*

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

*Effects on Prostate Specific Antigen (PSA)*
In clinical studies with Finasteride 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. Doubling the PSA level in men taking Finasteride 1mg should be considered before evaluating this test result.

This decrease in serum PSA concentrations needs to be considered, if during treatment with Finasteride Tablets 1mg, a patient requires a PSA assay. In this case doubling the PSA value should be considered before making a comparison with the results from untreated men.

*Effects on fertility*
See section 4.6 Fertility, pregnancy and lactation.

*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 during 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.

Sexual dysfunction that may contribute to mood alterations, including suicidal ideation, has been reported in some patients. Patients should be informed to seek medical advice in case they experience sexual dysfunction. Treatment discontinuation should be considered (see section 4.8).

Sexual dysfunction has also been reported without psychological effects, such as mood alterations or suicidal ideation.

A patient card reminding of the above is provided with the package of Finasteride 1 mg Film-coated Tablets.

**Important information regarding the ingredients this medicine**

**Lactose:** This medicine contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

## 4.5 Interaction with other medicinal products and other forms of interaction

Finasteride is metabolized primarily via, but does not affect, the cytochrome P450 3A4 system. Although the risk for 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 propranolol, digoxin, glibenclamide, warfarin, theophylline, and phenazone and no clinically meaningful 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 Fertility, pregnancy and lactation

*Pregnancy*
Finasteride 1mg is contraindicated for use in women due to risk in pregnancy.
Because of the ability of type II 5α-reductase inhibitors to inhibit conversion of testosterone to dihydrotestosterone (DHT) in some tissues, these drugs, including 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*
A small amount of finasteride, less than 0.001% of the 1 mg dose per ejaculation, has been detected in the seminal fluid of men taking Finasteride. 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.
Studies in Rhesus monkeys have indicated that this amount is unlikely to constitute a risk to the developing male foetus (see section 5.3)

During continual collection of adverse experiences, post marketing reports of exposure to finasteride during pregnancy via semen of men taking 1mg or higher doses have been received for eight live male births, and one retrospectively reported case concerned an infant with simple hypospadias. Causality cannot be assessed on the basis of this single retrospective report and hypospadias is a relatively common congenital anomaly with an incidence ranging from 0.8 to 8 per 1000 live male births. In addition, a further nine live male births occurred during clinical trials following exposure to finasteride via semen, during pregnancy, and no congenital anomalies have been reported.

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

*Breast-feeding*
It is not known whether finasteride is excreted in human milk.

*Fertility*
Long-term data on fertility in humans are lacking, and specific studies in subfertile men have not been conducted. The male patients who were planning to father a child were initially excluded from clinical trials. Although, 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 1mg has no or negligible on the ability to drive or use machines

## 4.8 Undesirable effects

The adverse reactions during clinical trials and/or post-marketing use are listed in the table below.
Frequency of adverse reactions is determined as follows:
Very Common (≥ 1/10); Common (≥ 1/100, < 1/10); Uncommon (≥ 1/1,000, < 1/100); Rare (≥1/10,000, < 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.

| | |
|---|---|
| **Immune system disorders:** | *Not known*: Hypersensitivity reactions, such as rash, pruritus, urticaria and angioedema including swelling of the lips, tongue, throat and face. |
| | |
| **Psychiatric disorders:** | *Uncommon**: Decreased libido.<br>*Uncommon*: Depression †<br>*Not known:* Anxiety, suicidal ideation. |
| **Cardiac disorders:** | *Not known*: Palpitation |
| **Hepatobiliary disorders:** | *Not known*: Increased hepatic enzymes |
| **Reproductive system and breast disorders:** | *Uncommon**: Erectile dysfunction, ejaculation disorder (including decreased volume of ejaculate).<br>*Not known*: Breast tenderness and enlargement, Testicular pain, haematospermia, infertility**.<br>**See section 4.4. |

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

† This adverse reaction was identified through 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.

Side effects, which usually have been mild, generally have not required discontinuation of therapy.

Finasteride for male pattern hair loss has been evaluated for safety in clinical studies involving more than 3,200 men. In three 12-month, placebo-controlled, double-blind, multicentre studies of comparable design, the overall safety profiles of Finasteride and placebo were similar. Discontinuation of therapy due to any clinical adverse experience occurred in 1.7% of 945 men treated with Finasteride and 2.1% of 934 men treated with placebo.

In these studies, the following drug-related adverse experiences were reported in ≥1% of men treated with Finasteride decreased libido (Finasteride, 1.8% vs. placebo, 1.3%) and erectile dysfunction (1.3%, 0.7%). In addition, decreased volume of ejaculate was reported in 0.8% of men treated with Finasteride and 0.4% of men treated with placebo. Resolution of these side effects occurred in men who discontinued therapy with Finasteride and in many who continued therapy. The effect of Finasteride on ejaculate volume was measured in a separate study and was not different from that seen with placebo.

By the fifth year of treatment with Finasteride, the proportion of patients reporting each of the above side effects decreased to <0.3%.

Finasteride has also been studied for prostate cancer risk reduction at 5 times the dosage recommended for male pattern hair loss. In a 7-year placebo-controlled trial

that enrolled 18,882 healthy men, of whom 9060 had prostate needle biopsy data available for analysis, prostate cancer was detected in 803 (18.4%) men receiving finasteride 5 mg and 1147 (24.4%) men receiving placebo. In the finasteride 5 mg group, 280 (6.4%) men had prostate cancer with Gleason scores of 7-10 detected on needle biopsy vs. 237 (5.1%) men in placebo group. Of the total cases of prostate cancer diagnosed in this study, approximately 98% were classified as intracapsular (stage T1 or T2). The relationship between long-term use of Finasteride 5 mg and tumours with Gleason scores of 7-10 is unknown.

In addition, the following have been reported in post-marketing use: persistence of sexual dysfunction (decreased libido, erectile dysfunction and ejaculation disorder) after discontinuation of treatment with Finasteride 1mg; male breast cancer (see section 4.4 Special warnings and precautions for use).

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.

***Reporting of suspected adverse reactions***

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

### 4.9 Overdose

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

No specific treatment of overdosage with finasteride is recommended.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 5α-reductase inhibitor

ATC code: D11AX10

***Mechanism of action***

Finasteride is a 4-azasteroid, which inhibits human Type 2 5α-reductase (present within the hair follicles) with greater than 100-fold selectivity over human Type 1 5α-reductase, and blocks the peripheral conversion of testosterone to the androgen dihydrotestosterone (DHT).

Finasteride is a competitive and specific inhibitor of type II 5α-reductase. Finasteride has no affinity for the androgen receptor and has no androgenic, anti-androgenic, oestrogenic, anti-oestrogenic, or progestational effects. Inhibition of this enzyme blocks the peripheral conversion of testosterone to the androgen DHT, resulting in significant decreases in serum and tissue DHT concentrations. Finasteride produces a rapid reduction in serum DHT concentration, reaching significant suppression within 24 hours of dosing.

Hair follicles contain type II 5α-reductase. In men with male pattern hair loss, the balding scalp contains miniaturized hair follicles and increased amounts of DHT. Administration of finasteride decreases scalp and serum DHT concentrations in these men. Men with a genetic deficiency of type II 5α-reductase do not suffer from male pattern hair loss. Finasteride inhibits a process responsible for miniaturization of the scalp hair follicles, which can lead to reversal of the balding process.

*Clinical efficacy and safety*

**Studies in men:**

Clinical studies were conducted in 1879 men aged 18 to 41 with mild to moderate, but not complete, vertex hair loss and frontal/mid-area hair loss.

In the two studies in men with vertex hair loss, (n=1553), 290 men completed 5 years of treatment with Finasteride 1mg vs 16 patients on placebo. In these two studies, efficacy was assessed by the following methods: (i) hair count in a representative 5.1cm$^2$ area of scalp, (ii) patient self assessment questionnaire, (iii) investigator assessment using a seven point scale, and (iv) photographic assessment of standardised paired photographs by a blinded expert panel of dermatologists using a seven point scale.

In these 5 year studies men treated with Finasteride 1mg improved compared to both baseline and placebo beginning as early as 3 months, as determined by both the patient and investigator assessments of efficacy. With regard to hair count, the primary endpoint in these studies, increases compared to baseline were demonstrated starting at 6 months (the earliest time point assessed) through to the end of the study. In men treated with Finasteride 1mg these increases were greatest at 2 years and gradually declined thereafter to the end of 5 years; whereas hair loss in the placebo group progressively worsened compared to baseline over the entire 5 year period. In Finasteride 1mg treated patients, a mean increase from baseline of 88 hairs [p <0.01; 95% CI (77.9, 97.80; n=433] in the representative 5.1 cm2 area was observed at 2 years and an increase from baseline of 38 hairs [p <0.01; 95% CI (20.8, 55.6); n=219] was observed at 5 years, compared with a decrease from baseline of 50 hairs

[p <0.01; 95% CI (-80.5, -20.6);n=47] at 2 years and a decrease from baseline of 239 hairs [p <0.01; 95% CI (-304.4, -173.4); n=15] at 5 years in patients who received placebo. Standardised photographic assessment of efficacy demonstrated that 48% of men treated with finasteride for 5 years were rated as improved, and an additional 42% were rated as unchanged. This is in comparison to 25% of men treated with placebo for 5 years who were rated as improved or unchanged. These data demonstrate that treatment with Finasteride 1mg for 5 years resulted in a stabilisation of the hair loss that occurred in men treated with placebo.
An additional 48-week, placebo-controlled study designed to assess the effect of Finasteride 1mg on the phases of the hair growth cycle (growing phase [anagen] and resting phase [telogen]) in vertex baldness enrolled 212 men with androgenetic alopecia. At baseline and 48 weeks, total, anagen and telogen hair counts were obtained in a 1-$cm^2$ target area of the scalp. Treatment with Finasteride 1mg led to improvements in anagen hair counts, while men in the placebo group lost anagen hair. At 48 weeks, men treated with Finasteride 1mg showed net increases in total and anagen hair counts of 17 hairs and 27 hairs, respectively, compared to placebo. This increase in anagen hair count, compared to total hair count, led to a net improvement in the anagen-to-telogen ratio of 47% at 48 weeks for men treated with Finasteride 1mg, compared to placebo. These data provide direct evidence that treatment with Finasteride 1mg promotes the conversion of hair follicles into the actively growing phase.

**Studies in women**
Lack of efficacy was demonstrated in post-menopausal women with androgenetic alopecia who were treated with finasteride 1 mg in a 12-month, placebo controlled study (n=137). These women did not show any improvement in hair count, patient self-assessment, investigator assessment, or ratings based on standardized photographs, compared with the placebo group.

## 5.2 Pharmacokinetic properties

*Absorption*
Relative to an intravenous reference dose, the oral bioavailability of finasteride is approximately 80%. The bioavailability is not affected by food. Maximum finasteride plasma concentrations are reached approximately two hours after dosing and 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.

At steady state following dosing with 1 mg/day, maximum finasteride plasma concentration averaged 9.2 ng/ml and was reached 1 to 2 hours post-dose; AUC (0-24 hr) was 53 ng•hr/ml.

Finasteride has been recovered in the cerebrospinal fluid (CSF), but the drug does not appear to concentrate preferentially to the CSF. A small amount of finasteride has also been detected in the seminal fluid of subjects receiving the drug.

*Biotransformation*
Finasteride is metabolised primarily via the cytochrome P450 3A4 enzyme subfamily. Following an oral dose of $^{14}$C-finasteride in man, two metabolites of the drug were identified that possess only a small fraction of the 5α-reductase inhibitory activity of finasteride.

*Elimination*
Following an oral dose of $^{14}$C-finasteride in man, 39% of the dose was excreted in the urine in the form of metabolites (virtually no unchanged drug was excreted in the urine) and 57% of total dose was excreted in the faeces.

Plasma clearance is approximately 165 ml/min.

The elimination rate of finasteride decreases somewhat with age. Mean terminal half-life is approximately 5-6 hours in men 18-60 years of age and 8 hours in men more than 70 years of age. These findings are of no clinical significance and hence, a reduction in dosage in the elderly is not warranted.

*Renal impairment*
No adjustment in dosage is necessary in non-dialysed patients with renal impairment

## 5.3 Preclinical safety data

*Mutagenicity/carcinogenicity*

Studies on genotoxicity and carcinogenicity have not revealed any hazards for humans.

*Reproduction disturbing effect including fertility*

In general, the findings in laboratory animals studies with oral finasteride were related to the pharmacological effects of 5α-reductase inhibition. The effects on embryonal and foetal development have been studied in rats, rabbits and rhesus monkeys. In rats treated with 5-5,000 times the clinical dose, a dose-related occurrence of hypospadias has been observed in male foetuses. Intravenous administration of finasteride to pregnant rhesus monkeys at doses as high as 800 ng/day during the entire period of embryonic and foetal

development resulted in no abnormalities in male foetuses. This represents at least 750 times the highest estimated exposure of pregnant women to finasteride from semen. In confirmation of the relevance of the Rhesus model for human foetal development, oral administration of finasteride 2 mg/kg/day (100 times the recommended human dose or approximately 12 million times the highest estimated exposure to finasteride from semen) to pregnant monkeys resulted in external genital abnormalities in male foetuses. No other abnormalities were observed in male foetuses and no finasteride-related abnormalities were observed in female foetuses at any dose. . In the rabbit study the foetuses were not exposed to finasteride during the period critical for genital development. Neither ejaculation volume, sperm count nor fertility were affected in the rabbit after treatment with 80 mg/kg/day, a dose that in other studies is shown to have pronounced weight lowering effect of accessory sexual glands. In rats treated for 6 and 12 weeks with 80 mg/kg/day (approx. 500 times the clinical exposure) no effect on fertility was observed. After 24-30 weeks treatment some reduced fertility and pronounced weight reduction of prostate and seminal vesicle were seen. All changes were reversible within a 6-week period. The reduced fertility has been shown to be due to impaired seminal plug formation, an effect that has no relevance to man. The development of the newborns and their reproduction capacity at the age of sexual maturation were without remark. After insemination of female rats with epididymis sperms from rats treated for 36 weeks with 80 mg/kg/day no effect was seen on a number of fertility parameters.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

**Tablet core**

Lactose monohydrate
Maize starch pregelatinised
Docusate sodium
Iron oxide yellow (E172)
Sodium starch glycollate
Microcrystalline cellulose
Colloidal anhydrous silica
Magnesium stearate

**Film-coating**

Opadry Pink consists of:

Hypromellose

Hydoxypropyl cellulose

Talc

Titanium dioxide (E171)

Iron oxide red (E172)

Iron oxide yellow (E172)

### 6.2 Incompatibilities

None

### 6.3 Shelf life

3 years

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

### 6.5 Nature and contents of container

White PVC/PE/PVDC/Al and/or Al/Al blister packs of 7, 28, 30, 84 or 98 tablets .Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

Crushed or broken tablets of finasteride should not be handled by women when they are or may potentially be pregnant (see section 4.6).

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

## 7 MARKETING AUTHORISATION HOLDER

Bristol Laboratories Limited,
Unit 3, Canalside,
Northbridge Road, Berkhamsted,
Herts, HP4 1EG, UK

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 17907/0497

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

28/04/2022

## 10 DATE OF REVISION OF THE TEXT

07/05/2026