Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Finasteride 1mg film-coated tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1 mg of finasteride.

Excipients with known effect
Each tablet contains 87.49 mg of lactose monohydrate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet (tablet).
Round biconvex red film-coated tablets with a 6.5 mm nominal diameter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Finasteride is indicated in men 18 – 41 years of age for the early stages of androgenetic alopecia. Finasteride stabilises the process of androgenetic alopecia. Efficacy in bitemporal recession and end-stage hair loss has not been established.

4.2 Posology and method of administration

Posology
One tablet (1 mg) daily with or without food.
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. Continued use is recommended to sustain benefit. If treatment is stopped, the beneficial effects begin to reverse by 6 months and return to baseline by 9 to 12 months.

Patients with renal impairment
No dosage adjustment is required in patients with renal insufficiency.

Method of administration
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 subsequent potential risk to a male foetus (see section 4.6). Finasteride tablets are coated and will prevent contact with the active substance during normal handling, provided that the tablets are not broken or crushed.

4.3 Contraindications

-Contraindicated in women (see section 4.6 and 5.1).
-Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

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.

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 should be considered before evaluating this test result.

Effects on fertility
See section 4.6.

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).
A patient card reminding of the above is provided with the package of Finasteride 1mg film-coated tablets.

Finasteride contains lactose
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Finasteride contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated 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.

Interaction studies have only been performed in adults.

4.6 Fertility, pregnancy and lactation

Pregnancy
Finasteride is contraindicated for use 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 (see section 6.6).

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 has no or negligible influence on the ability to drive and 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 to < 1/10); Uncommon (≥ 1/1,000 to < 1/100); Rare (≥ 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 reporting 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. *Uncommon*: Depression†. *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). *Not known*: Breast tenderness and enlargement, testicular pain, haematospermia, infertility **. **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 randomised controlled Phase III clinical trials (Protocols 087, 089 and 092) was not different between finasteride and placebo.

In addition, the following have been reported in post-marketing use: persistence of sexual dysfunction (decreased libido, erectile dysfunction and ejaculation disorders) after discontinuation of treatment with finasteride; male breast cancer (see section 4.4).

Drug-related sexual undesirable effects were more common in the finasteride-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-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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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 II 5α-reductase (present within the hair follicles) with greater than 100-fold selectivity over human type I 5α-reductase, and blocks the peripheral conversion of testosterone to the androgen

dihydrotestosterone (DHT). In men with male pattern hair loss, the balding scalp contains miniaturised hair follicles and increased amounts of DHT. Finasteride inhibits a process responsible for miniaturisation of the scalp hair follicles, which can lead to reversal of the balding process.

Clinical efficacy and safety

Studies in men:

The efficacy of finasteride 1 mg tablets was demonstrated in three studies in 1879 men 18 to 41 years of age with mild to moderate, but not complete, vertex hair loss and frontal/mid-area hair loss. In these studies, hair growth was assessed using four separate measures including hair count, ratings of photographs of the head by an expert panel of dermatologists, investigator assessment, and patient self-assessment.

In the two studies in men with vertex hair loss, treatment with finasteride 1 mg tablets was continued for 5 years, during which time patients improved compared to both baseline and placebo beginning at 3 to 6 months. While hair improvement measures compared to baseline in men treated with finasteride 1mg tablets were generally greatest at 2 years and gradually declined thereafter (e.g., hair count in a representative 5.1 cm^2 area was increased 88 hairs from baseline at 2 years and 38 hairs from baseline at 5 years), hair loss in the placebo group progressively worsened compared to baseline (decrease of 50 hairs at 2 years and 239 hairs at 5 years). Thus, although improvement compared to baseline in men treated with finasteride 1mg tablets did not increase further after 2 years, the difference between treatment groups continued to increase throughout the 5 years of the studies.

Treatment with finasteride 1mg tablets for 5 years resulted in stabilisation of hair loss in 90% of men based on photographic assessment and in 93% based on investigator assessment. In addition, increased hair growth was observed in 65% of men treated with finasteride 1 mg tablets based on hair counts, in 48% based on photographic assessment and in 77% based on investigator assessment. In contrast, in the placebo group, gradual hair loss over time was observed in 100% of men based on hair counts, in 75% based on photographic assessment and in 38% based on investigator assessment. In addition, patient self-assessment demonstrated significant increases in hair density, decreases in hair loss and improvement in appearance of hair after treatment over 5 years with finasteride 1 mg tablets (see table).

Percent of Patients Improved as Assessed by Each of the 4 Measures

	Year 1†		**Year 2††**		**Year 5††**	
	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
Global Photographic Assessment	*(N=720)* 48	*(N=709)* 7	*(N=508)* 66	*(N=55)* 7	*(N=279)* 48	*(N=16)* 6
Investigator Assessment	*(N=748)* 65	*(N=747)* 37	*(N=535)* 80	*(N=60)* 47	*(N=271)* 77	*(N=13)* 15
Patient self-assessment: satisfaction with hair appearance	*(N=750)* 39	*(N=747)* 22	*(N=535)* 51	*(N=60)* 25	*(N=284)* 63	*(N=15)* 20

† Randomization 1:1 Finasteride 1mg Tablets to placebo

†† Randomization 9:1 Finasteride 1mg Tablets to placebo

In a 12-month study, in men with frontal/mid-area hair loss, hair counts were obtained in a representative 1 cm2 area (approximately 1/5 the size of the area sampled in the vertex studies). Hair counts, adjusted to a 5.1 cm2 area, increased by 49 hairs (5%) compared to baseline and by 59 hairs (6%) compared to placebo. This study also demonstrated significant improvements in patient self-assessment, investigator assessment, and ratings of photographs of the head by an expert panel of dermatologists.

Two studies of 12- and 24-weeks duration showed that a dose 5-fold the recommended dose (finasteride 5 mg daily) produced a median decrease in ejaculate volume of approximately 0.5 mL (-25%) compared with placebo. This decrease was reversible after discontinuation of treatment. In a study of 48 weeks of duration, Finasteride 1 mg daily produced a median decrease in ejaculate volume of 0.3 mL (-11%) compared with a 0.2 mL (-8%) decrease for placebo. No effect was observed on sperm count, motility or morphology. Longer-term data are not available. It has not been feasible to undertake clinical studies, which directly elucidate possible negative effects on fertility. However, such effects are judged as very unlikely (see section 5.3).

Studies in women

Lack of efficacy was demonstrated in post-menopausal women with androgenetic alopecia who were treated with finasteride 1 mg for 12 months.

5.2 Pharmacokinetic properties

Absorption
The oral bioavailability of finasteride is approximately 80% and 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 is approximately 76 litres (44 – 96 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 very small amount of finasteride has also been detected in the seminal fluid of subjects receiving finasteride.

Studies in rhesus monkeys showed that this amount is not considered to constitute a risk to the developing male foetus (see section 4.6 and 5.3).

Biotransformation
Finasteride is metabolised primarily via, but does not affect, the cytochrome P450 3A4 system. Following an oral dose of ^{14}C-finasteride in man, two metabolites of finasteride 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, 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 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. Mean terminal plasma half-life is approximately 5-6 hours (3-14 hours) (in men more than 70 years of age 8 hours (6-15 hours)). These findings are of no clinical significance and hence, a reduction in dosage in the elderly is not warranted.

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

Renal impairment
In patients with chronic renal impairment, with creatinine clearances ranging from 9 – 55 ml/min, area under the curve, maximum plasma concentrations, half-life and protein binding of unchanged finasteride after a single dose of ^{14}C-finasteride were similar to values obtained in healthy volunteers.

5.3 Preclinical safety data

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

Reproduction disturbing effect including fertility
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. In rhesus monkeys, treatment with oral doses of 2 mg/kg/day has also resulted in external genital abnormalities.

Intravenous doses of up to 800 ng/day in rhesus monkeys have not shown any effects in male foetuses. This represents at least 750 times the highest estimated exposure of pregnant women to finasteride from semen of men taking 1 mg/day (see section 5.2). 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 effects on accessory sexual glands. In rats treated for 6 and 12 weeks with 80 mg/kg/day (approximately 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 glycolate (type A)
Cellulose, microcrystalline
Silica, colloidal anhydrous
Magnesium stearate
Water, purified

Film coating
Hydroxypropyl cellulose
Hypromellose
Talc
Titanium dioxide (E171)
Iron oxide red (E172)
Iron oxide yellow (E172)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.

6.5 Nature and contents of container

White PVC/PE/PVDC/Aluminium and/or Aluminium/Aluminium blisters packed in boxes of 14, 20, 28, 30, 50, 60 or 100 film-coated tablets.
Not all pack sizes may be marketed.

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

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 subsequent potential risk to a male foetus (see section 4.6). Finasteride tablets are coated and will prevent contact with the active substance during normal handling, provided that the tablets are not broken or crushed.

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

7 MARKETING AUTHORISATION HOLDER

Careforsons Ireland Limited
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Dublin 2
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8 MARKETING AUTHORISATION NUMBER

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