

CORE SAFETY PROFILE

Finasteride 1 mg

4.3 Contraindications

Contra-indicated in women: see 4.6 Pregnancy and lactation and 5.1 Pharmacodynamic properties.

Hypersensitivity to finasteride or to any of the excipients.

4.4 Special warnings and precautions for use

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

In 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. Doubling the PSA level in men taking finasteride should be considered before evaluating this test result.

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.

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

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.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interactions 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.

4.6 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 fetus when administered to a pregnant woman (see 6.6 Instructions for use/handling).

Lactation:

It is not known whether finasteride is excreted in human milk.

4.7 Effects on ability to drive and use machines

There are no data to suggest that finasteride affects 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 ($\geq 1/10$); Common ($\geq 1/100, < 1/10$); Uncommon ($\geq 1/1,000, < 1/100$); Rare ($\geq 1/10,000, < 1/1,000$); 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:	<i>Not known:</i> Hypersensitivity reactions, including rash, pruritus, urticaria and swelling of the lips and face.
Cardiac disorder:	<i>Not known:</i> Palpitation
Psychiatric disorders:	<i>Uncommon*:</i> Decreased libido. <i>Uncommon:</i> Depressed mood†.
Hepatobiliary disorders:	<i>Not known:</i> Increased hepatic enzymes.
Reproductive system and breast disorders:	<i>Uncommon*:</i> Erectile dysfunction, ejaculation disorder (including decreased volume of ejaculate). <i>Not known:</i> Breast tenderness and enlargement, Testicular pain, 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 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 erectile dysfunction after discontinuation of treatment with finasteride; male breast cancer (see 4.4 Special warnings and precautions for use).~~

*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 4.4 Special warnings and precautions for use).*

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.