Brand Names

Propecia, Proscar

Indication Specific Dosing

For the treatment of benign prostatic hyperplasia (BPH)

Oral dosage (e.g., Proscar and generic equivalents)

Adults

5 mg PO once daily.

For the treatment of male pattern hair loss (i.e., androgenetic alopecia), in patients with mild to moderate hair loss of the vertex and anterior mid-scalp area

Oral dosage (Propecia and generic equivalents)

Adults

1 mg PO once daily. Daily use for 3 months or more is necessary before benefit is observed. Continue use to sustain benefit; withdrawal of treatment leads to reversal of effect within 12 months.

For the treatment of hirsutism† in individuals with polycystic ovary syndrome

Oral dosage

Adults

2.5 to 5 mg PO once daily.

For prostate cancer prophylaxis†

Oral dosage

Adults

The risks of finasteride for prostate cancer prevention outweigh the benefits. In a 7-year placebo-controlled study, finasteride 5 mg PO once daily was shown to prevent or delay the development of prostate cancer in healthy men (>= 55 years of age) with a low risk of prostate cancer (PSA <= 3 ng/mL). Prostate specific antigen (PSA) levels, digital rectal exams, and biopsies were used to aid in the diagnosis of prostate cancer. Results showed that men receiving finasteride had a 26% decreased risk of being diagnosed with prostate cancer compared to placebo ($p < 0.0001$); however, the risk reduction was limited to Gleason score (GS) <= 6 cancers. There was an increased incidence of high-grade prostate cancer (GS 7—10) with finasteride compared to placebo (6.4% vs. 5.2%, respectively, $p = 0.005$). Finasteride was also associated with a higher incidence of sexual side effects versus placebo.

For the use in feminine-affirming therapy†

Oral dosage

Adults

1 to 5 mg PO once daily. Dose increases should be based on individual response and monitored hormone levels.

Adolescents

2.5 to 5 mg PO once daily. Dose increases should be based on individual response and monitored hormone levels.

For the treatment of hyperandrogenic symptoms associated with non-classic congenital adrenal hyperplasia†

Oral dosage

Adults

1 to 5 mg PO once daily in combination with an oral contraceptive.

Contraindications And Precaution

Drug Interactions

The coadministration of certain medications may lead to harm and require avoidance or therapy modification; review all drug interactions prior to concomitant use of other medications.

Hypersensitivity

This medication is contraindicated in patients with a history of hypersensitivity to it or any of its components. Cross-sensitivity with other 5-alpha-reductase inhibitors is possible.

prostate cancer

Prior to initiating treatment with finasteride, consideration should be given to other urological conditions that may cause similar symptoms, including the presence of pre-existing prostate cancer. Benign prostatic hypertrophy and prostate cancer may coexist. 5 alpha-reductase inhibitors, including finasteride, may increase the risk of development of high-grade prostate cancer. Careful monitoring and assessment of prostate specific antigen (PSA) tests is needed during finasteride use in all treated individuals, and especially in people with existing prostate cancer or at risk for prostate cancer.

hepatic failure

Finasteride should be used with caution in people with hepatic failure, as finasteride is metabolized extensively in the liver and exposure could be higher in these individuals. Data are lacking in people with hepatic impairment.

blood donor

People treated with finasteride should not be a blood donor until at least 1 month has passed following their last dose. The purpose of this deferred period is to prevent administration of finasteride to a pregnant individual receiving a blood transfusion. Serum levels of finasteride may be detectable following termination of therapy.

people who can cause pregnancy in others, people who may become pregnant, reproductive risk

Counsel patients about the reproductive risk associated with finasteride. In people who can cause pregnancy in others, there have been postmarketing reports of male infertility and/or poor seminal quality; normalization or improvement of seminal quality has been reported after discontinuation of finasteride. People who may become pregnant should not handle crushed or broken finasteride tablets because of possible exposure of a male fetus. Finasteride tablets are coated and will prevent skin contact during normal handling if the tablets have not been crushed or broken.

breast-feeding

Avoid use of finasteride during breast-feeding. Finasteride is not indicated for use in lactating individuals and has not been studied in breast-feeding. There is no information on the presence of finasteride in human milk, its effects on the breast-fed child, or its effects on milk production.

pregnancy

Finasteride is contraindicated for use during pregnancy. Finasteride may cause fetal harm. Finasteride and other 5-alpha-reductase inhibitors, by inhibiting the conversion of testosterone to 5-alpha-dihydrotestosterone (DHT), have the ability to cause external genital abnormalities in the male fetus. This action has been confirmed by animal studies, including in rhesus monkeys. The finasteride tablets are coated and will prevent finasteride skin contact during normal handling if the tablets have not been crushed or broken. Pregnant people should not handle crushed or broken finasteride tablets because of possible exposure of a male fetus; if contact occurs, wash the contact area immediately with soap and water. With regard to potential finasteride exposure to a pregnant individual through semen of a partner treated with finasteride, one study measured finasteride concentrations in semen and distribution of finasteride into the semen appears to be well below the threshold concentration associated with fetal anomalies in animals.

Pregnancy And Lactation

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Interactions

Saw Palmetto, Serenoa repens: (Moderate) Saw palmetto may inhibit 5 alpha-reductase, preventing the conversion of testosterone to dihydrotestosterone. This action is similar to the action of 5-alpha reductase inhibitors, such as dutasteride and finasteride. Co-use is likely to be common by patients, but the effects of co-use are not known. In theory, the effects could be additive, but it is not known if the added effects would be beneficial or harmful. Clinicians should be alert for any unusual effects if patients ingest saw palmetto supplements while taking 5-alpha reductase inhibitors.
Soy Isoflavones: (Minor) Theoretically, because the soy isoflavones appear to inhibit type II 5-alpha-reductase, the soy isoflavones may have additive effects with other 5-alpha reductase inhibitors.
Terazosin: (Minor) Terazosin has been reported to increase peak concentrations of finasteride by 16% and AUC by 31% when the two agents are coadministered. The interaction is of minor importance.

Adverse Reaction

breast cancer, breast enlargement, decreased ejaculate volume, depression, ejaculation dysfunction, gynecomastia, hematospermia, impotence (erectile dysfunction), libido decrease, mastalgia, new primary malignancy, orgasm dysfunction, suicidal ideation, testicular pain

In a long-term (4 years) clinical trial in men with benign prostatic hypertrophy (BPH), the most frequently reported adverse reactions to finasteride were related to sexual function and breast-related events. At 1 year, the adverse reactions reported to be drug-related were impotence (erectile dysfunction), libido decrease, decreased ejaculate volume, ejaculation dysfunction, breast enlargement, and breast tenderness (mastalgia). There was no significant difference between finasteride and placebo in the incidences of impotence, decreased libido, and ejaculation dysfunction in years 2 to 4 of the study. In controlled trials of finasteride for the treatment of male pattern hair loss, 1.4% of patients discontinued therapy due to adverse events; discontinuation of therapy because of a drug-related sexual adverse experience occurred in 1.2% of patients. The following adverse events were reported in finasteride-treated patients: libido decrease (1.8%), erectile dysfunction (impotence) (1.3%), and ejaculation disorder (1.2%), primarily decreased ejaculate volume. The incidence of each of the above adverse effects decreased to 0.3% or less by the fifth year of treatment. Gynecomastia has been the most frequently reported adverse effect with use of finasteride since the drug was

marketed. Data indicate the onset of gynecomastia has ranged from 14 days to 2.5 years (median: 180 days) of treatment. Thirty percent had unilateral gynecomastia, 25% had bilateral involvement, and in other cases this information was not specified. Twenty-seven percent of patients were also taking other medications that are known to cause gynecomastia. Gynecomastia resolved either completely or partially in 80% of subjects after finasteride was discontinued; however, in at least 2 cases, a new primary malignancy of primary intraductal breast cancer subsequently developed. Male breast cancer has been reported during postmarketing experience. In one trial where patients were randomized to receive finasteride 5 mg/day, doxazosin 4 or 8 mg/day, a combination of the two drugs, or placebo, four patients reported breast cancer as an adverse experience; three of the patients were receiving finasteride therapy and one patient was receiving combination therapy. Other postmarketing adverse reactions reported with finasteride use have included decreased libido and libido disorders that continued after discontinuation of treatment, depression, suicidal ideation and behavior, hematospermia, testicular pain that continued after discontinuation of treatment, problems with ejaculation or erectile dysfunction that continued after stopping the medication, and orgasm dysfunction or other orgasm disorders.

infertility, oligospermia, spermatogenesis inhibition

Finasteride may cause poor sperm quality, including spermatogenesis inhibition or oligospermia, decreased sperm motility, or decreased semen volume. Consider the potential effects on semen when assessing a male with infertility who is receiving finasteride treatment. In a 52-week, randomized, double-blind, placebo-controlled study in healthy men, finasteride (5 mg PO once daily) significantly decreased total sperm count (-34.3%) compared to baseline at 26 weeks but not at 52 weeks or at the 24-week follow-up. Semen volume was decreased at 52 weeks for finasteride (-14.5%), but the effect was not statistically significant. Sperm concentration was decreased by finasteride (-7.4%) but was not significant for either drug. Significant reductions of 6% to 12% in sperm motility were observed during treatment. Sperm morphology was not affected. One subject taking finasteride had decreases in sperm count of more than 90% of baseline values at 52 weeks; partial recovery was noted at the 24-week follow-up. During postmarketing surveillance, male infertility and/or poor seminal quality following treatment discontinuation have been reported. Normalization or improvement of seminal quality has also been reported after discontinuation of finasteride.

angioedema, pruritus, rash, urticaria

During clinical trials, rash (unspecified) was reported in approximately 0.5% of patients receiving finasteride treatment. Hypersensitivity reactions have been reported with

finasteride use postmarketing and have included rash, pruritus, urticaria, and angioedema (including swelling of the lips, tongue, throat, and face).

teratogenesis

By inhibiting the conversion of testosterone to DHT, finasteride and other 5-alpha-reductase inhibitors have the ability to cause teratogenesis, specifically abnormalities in the external genitalia of the male fetus (e.g., hypospadias).

Description

Finasteride is a 5-alpha reductase inhibitor used to treat symptomatic benign prostatic hyperplasia (BPH). Finasteride is also used for treating hair loss in men (androgenic alopecia) and has been shown to be effective for mild to moderate hair loss of the vertex and anterior mid-scalp area; efficacy in bitemporal recession has not been established. Finasteride is also used investigationally as an alternative agent for treating hirsutism. According to the American Urological Association (AUA) guidelines, 5-ARIs (e.g., dutasteride, finasteride) may be used to prevent the progression of lower urinary tract symptoms (LUTS) secondary to BPH and to reduce the risk of urinary retention and future prostate-related surgery. The guidelines further state that 5-ARIs are appropriate and effective alternatives for men with LUTS secondary to BPH who have demonstrable prostate enlargement. 5-ARIs should not be used in the absence of prostatic enlargement. Results from two large, randomized controlled trials indicate that there may be a decreased risk of low-grade prostate cancer but an increased risk of high-grade prostate cancer in patients receiving 5-ARIs. Therefore, the known treatment benefits of 5-ARIs should be weighed against the potential increased risk of prostate cancer. Rule out other urological diseases prior to treatment with finasteride and periodically thereafter.
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Because 5-ARIs inhibit the conversion of testosterone to dihydrotestosterone which can cause abnormalities in the external genitalia of the male fetus, pregnant women or women trying to conceive should not handle 5-ARIs since absorption through the skin may result in fetal exposure and severe adverse outcomes. Finasteride was initially approved by the FDA in 1992 for the treatment of BPH and was approved by the FDA in 1997 for the treatment of androgenetic alopecia.

Mechanism Of Action

Finasteride is a synthetic 4-aza analog of testosterone that acts as a competitive, specific inhibitor of type II 5-alpha-reductase, an intracellular enzyme that converts testosterone to the potent androgen 5-alpha-dihydrotestosterone (DHT). The type II 5alpha-reductase

isozyme is primarily found in prostate, seminal vesicles, epididymides, and hair follicles, as well as liver. The type II isozyme is responsible for two-thirds of circulating DHT. DHT is the primary androgen that stimulates the development of prostate tissue. When used for the treatment of benign prostatic hyperplasia, as the enzymatic conversion from testosterone to DHT is inhibited, a desirable reduction in prostate hypertrophy is achieved, and urine flow should be improved. In male pattern hair loss, the balding scalp contains miniaturized hair follicles and increased amounts of DHT compared with hairy scalp. Finasteride decreases scalp and serum DHT concentrations, thus interrupting a key factor in the development of androgenetic alopecia in those patients genetically predisposed. Finasteride does not appear to affect circulating concentrations of cortisol, estradiol, prolactin, thyroid-stimulating hormone, thyroxine or cholesterol. Research to date also suggests that finasteride does not affect the hypothalamic-pituitary-testicular-axis.

Pharmacokinetics

Finasteride is administered orally in men. Approximately 90% is bound to plasma proteins; yet the drug has been found to cross the blood-brain barrier. Finasteride generally does not affect other hormones. Finasteride has minimal distribution into semen. Data from 2 studies found semen drug concentrations ranged from undetectable (less than 0.1 ng/mL) to 10.54 ng/mL following daily treatments for 6 to 24 weeks. Daily dosing causes accumulation to occur, with plasma concentrations increasing by 50% over those observed from a single dose. The mean plasma elimination half-life of finasteride is 6 hours (range, 3 to 16 hours); however, the turnover rate for the type II 5-alpha-reductase enzyme complex is slow, with a turnover half-life of approximately 30 days. After oral dosing, about half of the unchanged drug is excreted in the feces, and one-third is metabolized in the liver to the 17-carboxylic acid, which is then excreted in the urine (39%) and the feces (57%).

A single 5 mg oral dose rapidly reduces serum DHT concentrations by as much as 70%, with the maximum reduction occurring at about 8 hours. The effect lasts for at least 24 hours, so once daily dosing is appropriate. Actual clinical effects, however, are not realized for 3 to 6 months after beginning therapy.

Affected cytochrome P450 (CYP450) isoenzymes and drug transporters: CYP3A4, UGT1A4
While finasteride is metabolized by hepatic CYP3A4 isoenzymes, no drug interactions of clinical importance have been identified, likely due to the hormonal mechanisms of action and relatively large therapeutic window of effect. Finasteride does not appear to affect the CYP450-linked drug metabolizing enzyme system. Compounds that have been tested in man have included antipyrine, digoxin, propranolol, theophylline, and warfarin

and no clinically meaningful interactions were found. Finasteride has not been associated with clinically important drug interactions during clinical trials, including a 4-year safety trial of 3,040 males aged 45 to 78 years. Finasteride markedly inhibited UGT1A4 activity in vitro in a drug transporter study; however, the data strongly suggested that finasteride is unlikely to cause clinically significant drug-drug interactions mediated via inhibition of the hepatic UGT enzymes involved in drug metabolism in vivo.

Route-Specific Pharmacokinetics

- **Oral Route**

The mean bioavailability following a single dose of finasteride is about 63%; however, bioavailability is highly variable (range, 34% to 108%). Bioavailability is not affected by food, and maximum plasma concentrations (Cmax) are attained within 1 to 2 hours post dose.

- **Hepatic Impairment**

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

- **Renal Impairment**

Following administration of a single dose, the pharmacokinetics of finasteride (i.e., exposure, peak concentration, half-life, and protein binding) in patients with chronic renal impairment with a creatinine clearance (CrCl) 9 to 55 mL/minute were similar to those observed in healthy volunteers; however, plasma concentrations of the metabolites were significantly higher in patients with renal impairment. No dose adjustments are needed for decreased renal function.

- **Geriatric**

Elimination of finasteride is reduced somewhat in the elderly, but no dosage adjustment is necessary.

Administration

For storage information, see the specific product information within the How Supplied section.

Hazardous Drugs Classification
NIOSH 2024 List: Table 2
Observe and exercise appropriate precautions for handling, preparation, administration, and disposal of hazardous drugs.
Use gloves to handle; double chemotherapy gloves and a protective gown are needed if manipulation is necessary. Cutting, crushing, or otherwise manipulating tablets/capsules will increase exposure.

Oral Administration

May administer without regard to meals.
People who are pregnant or may get pregnant must not handle/administer broken or crushed finasteride tablets; the active ingredient could cause fetal harm. Exposure to whole tablets is not expected to cause harm as long as the tablets are not swallowed.

Maximum Dosage Limits

- **Adults**
  Males: 5 mg/day PO for benign prostatic hyperplasia (BPH); the manufacturer literature states that patients have received up to 80 mg/day PO for three months without adverse effects; however, it is not clear if the dose was used therapeutically or provided additional benefit over the usual dose range. Maximum dose-response is 1 mg/day PO for alopecia.
- **Elderly**
  Males: 5 mg/day PO for benign prostatic hyperplasia (BPH); the manufacturer literature states that patients have received up to 80 mg/day PO for three months without adverse effects; however, it is not clear if the dose was used therapeutically or provided additional benefit over the usual dose range. Maximum dose-response is 1 mg/day PO for alopecia.
- **Adolescents**
  Not indicated.
- **Children**
  Not indicated.

Dosage Forms

- ENTADFI 5mg-5mg Capsule
- Finapod Solution 0.1%-7% for Compounding
- Finapodtar Solution 0.1%-7%-0.025% for Compounding
- Finasteride 0.1% Topical solution, Minoxidil 7% Topical solution with Compounding Solution
- Finasteride 1mg Oral tablet [Alopecia]
- Finasteride 5mg Oral tablet [Benign Prostatic Hyperplasia]
- Finasteride Bulk powder
- Propecia 1mg Tablet [Alopecia]
- Proscar 5mg Tablet

- Proscar 5mg Tablet

Dosage Adjustment Guidelines

Hepatic Impairment

Finasteride should be initiated with caution in patients with hepatic disease. Since finasteride is metabolized extensively in the liver, reduced metabolism is possible. The effect of hepatic impairment on finasteride pharmacokinetics has not been studied.

Renal Impairment

Specific guidelines for dosage adjustments in renal impairment are not available; it appears that no dosage adjustments are needed.