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I acknowledge receipt of this finasteride information sheet.

Please print:

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Last Name First Name

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Signature Date

Information on Finasteride (Propecia®)

Propecia ® (finasteride 1mg) is an oral medication, manufactured by Merck Pharmaceuticals, that blocks the conversion of testosterone to dihydrotestosterone (DHT), the hormone largely responsible for male pattern baldness. It does this by inhibiting the action of the type II 5-alpha reductase enzyme that is present in higher concentration in and around the hair follicles of balding men with androgenetic alopecia.

Finasteride is the only FDA approved medication for hair loss in men. It became available as the brand Propecia (finasteride 1mg) in December 1997 and is now generic. The same drug, under the brand name Proscar (finasteride 5mg) has been approved for the treatment of prostate enlargement since 1992.

Finasteride produces a rapid decrease in serum DHT concentration. Lowering DHT appears to inhibit the miniaturization (shrinking) of affected hair follicles and helps restore miniaturized hair follicles to regrow visible hair. Circulating levels of testosterone and estradiol were increased by approximately 15% as compared to baseline in the first year of treatment, but these levels were within normal range.

Studies have shown that after five years of treatment, 90% of men taking finasteride maintained their hair or increased hair growth. At five years, 48% of men treated with PROPECIA demonstrated an increase in hair growth, 42% were rated as having no change (no further visible progression of hair loss from baseline) and 10% were rated as having lost hair when compared to baseline. In comparison, 6% of men treated with placebo demonstrated an increase in hair growth, 19% were rated as having no change and 75% were rated as having lost hair when compared to baseline.

The effects of finasteride are confined to areas of the scalp that are thinning, but where there is still some hair present. It does not seem to grow hair in completely bald areas. Therefore, the major benefit of finasteride seems to be in its ability to slow down or halt hair loss or regrow hair in parts of the scalp where the hair is thin. The effects of finasteride peak at one to two years. Finasteride continues to be effective for at least 5 years in slowing down or preventing additional hair loss.

The benefits of finasteride will stop if the medication is discontinued. Over the two to six months following discontinuation, the hair loss pattern will generally return to the state that it would have been reached if the medication had never been used.

Using PROPECIA

PROPECIA is an oral medication that should be taken once daily with or without meals. Patients must take Finasteride for one year or longer before its effects in preventing hair

loss and re-growing hair can be accurately assessed. Finasteride takes up to a year or more to exert its full effects in both preventing hair loss and in re-growing hair.

During the first six months you may note some thinning of your existing hair. This may be due to either progression of your hair loss before finasteride has had a chance to work or some shedding of miniaturized hair that makes way for the new healthy hair to grow. It is important to be patient during this period. You should continue the medication for at least <u>one year</u> before you and your doctor can assess its benefits.

Sexual Side Effects

Side effects from finasteride at the 1-mg dose are uncommon. The one-year drug related side effects were 1.5% greater than in the control group. The data showed that 3.8% of men taking finasteride 1mg experienced some form of sexual dysfunction verses 2.1% in men treated with a placebo. The five-year side effects profile included: decreased libido (0.3%), erectile dysfunction (0.3%), and decreased volume of ejaculate. Recent studies indicate that the incidence may be significantly higher.

Most reported cases of sexual dysfunction occurred soon after starting the medication, but there have been reports of sexual dysfunction that have occurred at later points in time. The sexual side effects were reversed in those who discontinued therapy, and in 58% of those who continued treatment. After the medication was stopped, side effects generally disappeared within a few weeks to months. There have been anecdotal reports where side effects have persisted after discontinuation of therapy. This had been referred to as "Post-finasteride syndrome" (see below).

When finasteride is discontinued, only the hair that had been gained or preserved by the medication is lost. In effect, the patient returns to the level of balding where he would have been had he never used the drug in the first place. No drug interactions of clinical importance have been identified.

Finasteride Label Changes – 2012 (Summary)

On April 11, 2012, the U.S. Food and Drug Administration (FDA) announced changes to the professional labels for Propecia (finasteride 1 mg) and Proscar (finasteride 5 mg) to expand the list of sexual adverse events reported to FDA as some of these events have been reported to continue after the drug is no longer being used (note that erectile dysfunction after stopping use of these drugs was added as a known event in 2011). The new label changes include:

- A revision to the Propecia label to include libido disorders, ejaculation disorders, and orgasm disorders that continued after discontinuation of the drug.
- A revision to the Proscar label to include decreased libido that continued after discontinuation of the drug.

- A revision to both the Propecia and Proscar labels to include a description of reports of male infertility and/or poor semen quality that normalized or improved after drug discontinuation.

Despite the fact that clear causal links between finasteride (Propecia and Proscar) and sexual adverse events have NOT been established, the cases suggest a broader range of adverse effects than previously reported in patients taking these drugs.

Only a small percentage of men using these drugs have experienced a sexual adverse event. During treatment with Propecia, 3.8% of men had reported one or more adverse sexual experiences as compared to 2.1% men who did not receive Propecia (received placebo). This represents a 1.7% difference.

For Propecia, the FDA's Agency's Adverse Events Reporting System (AERS) database between 1998 and 2011 found 59 cases of reported sexual dysfunction that lasted for at least three months following discontinuation of Propecia, and included erectile dysfunction, decreased libido, problems with ejaculation and orgasm disorders.

The FDA has not established a cause and effect relationship between finasteride and the sexual adverse events that continued after stopping drug use. The FDA believes that finasteride remains a safe and effective drug for its approved indications. Healthcare professionals and patients should consider this new label information when deciding the best treatment option.
See: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm299754.htm

Post-Finasteride Syndrome (PFS)
Post Finasteride Syndrome (PFS) is the term applied to reports of significant sexual, neurological and physical side effects, such as erectile dysfunction, depression, clouded thinking "brain fog," penile numbness, penile shrinkage, and loss of libido, that persist in men who have taken and then discontinued finasteride.

A personal or family history of psychiatric illness may increase the risk of developing PFS. Some of these may include; anxiety, depression, panic disorder, obsessive compulsive disorder (OCD) and Body Dysmorphic Syndrome (BDS).

Studies in progress are trying to better understand the incidence, cause and risk factors of PFS. More information on PFS can be found on the website: http://www.pfsfoundation.org/

Fertility
Finasteride may decrease fertility in some men. The effects may be due to changes in the composition of ejaculate and/or a reduction in sperm count. The effects appear to be

reversible on discontinuing the medication.

Effects on Breast Tissue
Adverse reactions related to the breast, including breast tenderness, breast enlargement (gynecomastia), and nipple discharge, occurred in less than 1% of men taking finasteride 1-mg (PROPECIA). In rare cases, breast cancer has been reported in male patients taking finasteride.

Other Adverse Reactions
Other uncommon side effects included hypersensitivity reactions including rash, pruritus (itching), urticaria (hives), swelling of the lips and face, testicular pain, mood changes (including depression) and cognitive changes (sometimes referred to as "brain fog").

Finasteride and Prostate Cancer
The results of an 18-year, 18,000 patient study published 8-14-2013 in the New England Journal of Medicine, showed that taking finasteride 5mg a day does not increase the likelihood of death from prostate cancer. Early results from the same study had suggested that finasteride might increase the risk of developing higher grade tumors; however, follow-up results from the long-term study show that men taking the drug do not have an increased risk.

Additionally, the results of the study show that taking finasteride actually decreases the likelihood of a diagnosis of prostate cancer in men by 30% and a diagnosis of "low-grade" cancer in men by 43%. By shrinking the healthy prostate tissue, finasteride may decrease the chance of a false positive result in PSA screening tests and may avoid unnecessary surgery.

Caution during Pregnancy
Women should not handle crushed or broken PROPECIA tablets when they are pregnant, or may potentially be pregnant, because of the possibilities of absorption of finasteride and the subsequent potential risk to a male fetus. PROPECIA tablets are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed. Exposure of pregnant women to semen from men treated with PROPECIA has not been shown to pose any risk to the fetus.

Blood Donation
Patients taking finasteride should not donate blood as this blood may potentially be given to pregnant women.

Effects on PSA

Finasteride causes a decrease in serum PSA (prostate specific antigen) by approximately 40-50% in normal men. Since PSA levels are used to screen for prostate enlargement and prostate cancer, it is important that your personal physician is aware that you are taking Propecia (finasteride) so that he/she may take this into account when interpreting your PSA results.

Prostate Cancer Screening

In 2018, the US Preventive Services Task Force Recommendation Statement regarding screening for prostate cancer included the following: For men aged 55 to 69 years, the decision to undergo periodic prostate-specific antigen (PSA)-based screening for prostate cancer should be an individual one. The reason is that although it offers a small potential benefit in decreasing the morbidity of prostate cancer, there are potential risks from the testing itself. You should discuss the need for testing with your primary doctor or urologist. Routine prostate screening is not recommended for persons age 70 and older.

It is important that you read the manufacturer's Patient Information that comes with your medication.