

## Propecia Consent

**Finasteride** 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 androgenic alopecia.

Finasteride is the only FDA approved medication for hair loss in men. It became available as the brand Propecia (finasteride 1 mg) in December 1997. It 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.

### Long-Term Benefits and Risks

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.

Finasteride has been in clinical use for 20 years. PROPECIA was developed based on a naturally occurring model found in a population of men with type II 5 $\alpha$ -reductase deficiency. In this population, type II 5 $\alpha$ -reductase deficiency decreased conversion of testosterone into dihydrotestosterone (DHT). This male population did not experience male pattern hair loss any long-term adverse effects.

### PROPECIA and Hair Transplantation

PROPECIA can be a useful adjunct to surgical hair restoration. It maintains hair or increases hair growth in 90% of patients. PROPECIA works well in the younger patient who may not yet be a candidate for hair transplantation. PROPECIA is less effective in the front part of the scalp, the area where surgical hair restoration can offer the greatest cosmetic improvement. It can re-grow, or stabilize hair loss in the back part of the scalp where hair transplantation may not always be indicated.

### 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 one year 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 versus 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.

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. There have been anecdotal reports where side effects have persisted after discontinuation of therapy. This had been referred to as “Post-finasteride syndrome”.

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 1mg) and Proscar (Finasteride 5mg) 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 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. 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 or breast enlargement (gynecomastia), occurred in 0.4% of men taking Finasteride 1mg (Propecia), but this was no greater than in the control group. In a large study published in the Journal of Urology in 2013, the authors reported: “The lack of an association in our study suggests breast cancer development should not influence prescribing of 5ARI therapy.”

### **Other Adverse Reactions**

Other, uncommon side effects, included hypersensitivity reactions including rash, pruritus (itching), urticarial (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 08/14/2013 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 decreases the chances of a false positive result in PSA screening tests and can 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 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 woman.

### **Generic Finasteride**

For those wanting to take generic Finasteride, we recommend buying a pill cutter at the pharmacy and taking ¼ of a 5mg tablet every day. Although there is no scientific data insuring that this method of taking Finasteride will be as effective as Propecia 1mg a day, the pharmacology of the drug suggests that these methods are equivalent. Please divide only one pill at a time. The pill does not need to be divided into 4 equal parts.

When dividing these tablets, remember that there is a potential risk to pregnant women from handling broken or crushed tablets (see Caution during Pregnancy).

### **Off-Label Dosing**

There are no scientific studies that prove that increasing the dose will have any additional beneficial effects on hair loss. There are published data demonstrating that 5mg is no better than 1mg in controlled clinical trials. In practice, however, doctors may increase the dose when someone has been on the same dose of medication for 3- years and then stops responding (begins to lose hair after being stable). It has been our experience that increasing the dose may enable the medication to continue to be effective. It is important to understand that increasing the dose is an off-label use of this medication. It may increase the incidence of adverse reactions. When increasing the dose, we generally use generic Finasteride 5mg that is taken whole or broken into parts (see Caution during Pregnancy).

### **Effects on PSA**

Finasteride causes a decrease in serum PSA (prostate specific antigen) by approximately 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**

The American Cancer Society and the American Urological Association recommend the following screening ages:

- Age 50 for men who are at average risk of prostate cancer and are expected to live at least 10 more years.
- Age 45 for men at high risk of developing prostate cancer: African American men and men who have a first-degree relative (father, brother, or son) diagnosed with prostate cancer younger than age 65.
- Age 40 or men at even higher risk (those with several first-degree relatives who had prostate cancer at an early age).
- Regardless of age, yearly screening for PSA level is 2.5ng/ml or higher, and every 2 years for less than 2.5ng/ml.

An evaluation should include a rectal examination, a PSA, and other tests that your examining physician feels are appropriate. The above are general guidelines recommended for men regardless of whether they use



Finasteride or not. Specific recommendations for each patient should be based upon the judgment of his own physician.

**Dutasteride** which is similar medication to Finasteride may have the same side effects described above including “the post-finasteride syndrome”. Dustasteride needs the same follow-up as Finasteride.

\*\*\*\***Patient Initial:**\_\_\_\_\_ **Date:**\_\_\_\_\_

### Prescriptions

Your first prescription

**Please read Merck’s Patient Information on your prescription bottle.**

\*\*\*\* I acknowledge that the doctor has discussed with me the use and potential side effects of Finasteride (Propecia, Proscar), as well as Post Finasteride Syndrome (PFS), and that all of my questions have been answered. I acknowledge receipt of the Finasteride information sheet.

**PLEASE PRINT:**

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