

# Anderson Center for Hair – Patient Consent form for Propecia (finasteride) 1mg

## Information on Finasteride and PROPECIA®

Finasteride is an oral medication, manufactured by Merck Pharmaceuticals, and now by many other pharmaceutical companies, 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 (e.g.: male pattern baldness). Finasteride is the only FDA approved medication for hair loss in men. It became available as the brand Propecia (finasteride 1mg) in December 1997. 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.

In the "Hair Count Clinical Study," hair counts showed an average gain of 277 hairs per one-inch circle at the end of five years. These hairs were significantly larger than the fine, miniaturized hair characteristic of balding. In the "Hair Weight Clinical Study," 34% mean hair mass/weight difference was observed between PROPECIA and placebo at 96 weeks.

## Effectiveness on the Front of the Scalp

The indication for PROPECIA includes the treatment of hair loss in the front part of the scalp. There are published data demonstrating improvement in a controlled clinical trial of men with frontal hair loss as well.

## Long-Term Benefits and Risks

The effects of finasteride are confident 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, a major benefit of finasteride seems to be 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 over 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 to dihydrotestosterone (DHT). This male population did not experience male pattern hair loss or any long-term adverse effects.

## PROPECIA and Hair Transplantation

PROPECIA can be a useful adjunct to surgical hair restoration for a number of reasons. 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, there are 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.

In the long-term, finasteride may allow the hair restoration surgeon to create more density in the most cosmetically important areas (such as the front part of the scalp), since keeping reserves for future hair loss in other areas will be of less concern.

## 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 1mg dose are uncommon. The one-year drug related side effects were 1.5% greater than in the control (eg: placebo) group. The data showed that 3.8% of men taking finasteride experienced some form of sexual dysfunction versus 2.1% in the men treated with a placebo. The five-year side effects 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, even after just a few doses. This has been referred to as "Post-finasteride syndrome" or PFS. PFS is not currently well understood, and seems to affect a very small fraction of users. At a recent lecture, a neuro-endocrinologist who treats patients with PFS claimed to know of about 500 patients with PFS. This is out of 27 million patient-years of use of PROPECIA/finasteride 1mg per day.

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 side 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 casual 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% of 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.

<http://www.fda.gov/safety/medwatch/safetyinformation/ucm208701.htm>

#### **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 1 mg (PROPECIA), but this was no greater than in the control (eg: placebo) 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 5 alpha reductase inhibitor therapy."

#### **Other Adverse Reactions**

Other, uncommon side effects, included hypersensitivity reactions including rash, pruritis (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 August 14, 2013 in the New England Journal of Medicine, showed that taking finasteride 5 mg 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 screening tests and can avoid unnecessary surgery.

#### **Off-Label Use of Finasteride in Women**

Although finasteride is being prescribed for the treatment of female pattern hair loss (androgenetic alopecia), it is not FDA approved for use in women. As such, the safety profile for the use of finasteride in women has not been established.

As there may be an association with breast cancer, a personal or family history of breast cancer is a contraindication for the off-label use of this medication.

A recent study was conducted to evaluate the efficacy of finasteride in postmenopausal women. After one year of use, there was no increased hair growth and the progression of thinning was not slowed down. It is possible that the low DHT levels observed in postmenopausal women are responsible for the lack of significant response to finasteride or that hair loss in this group is not related to androgens at all. The safety profile for the use of finasteride in postmenopausal women has not been established.

#### **Caution during Pregnancy**

Finasteride use is contraindicated in woman when they are, or may be, pregnant due to the risk of developmental abnormalities in a male fetus. Woman should not handle crushed or broken PROPECIA tablet 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 show to pose any risk to the fetus.

#### **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 5 mg is not better than 1 mg in controlled trials. In practice, however, we sometimes increase the dose when someone has been on the same dose of medication for 3-5 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.

#### **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 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 or she may take this into account when interpreting your PSA test 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 for 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 if 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 patients should be based on the judgment of his own physician.

#### **Prescriptions**

Your first prescription for PROPECIA (finasteride 1mg) will be for a 12-month supply. You are encouraged to return to our office for follow-up evaluations. At each visit, you will be examined and any new information regarding finasteride and/or other therapies will be communicated to you. You will be responsible for obtaining urology evaluations if appropriate (see Prostate Cancer Screening). If you experience any problems or adverse reactions while taking finasteride, please contact us and/or your prescribing physician. Please also read Merck's Patient Information about finasteride 1mg.

Signature \_\_\_\_\_

Print Name \_\_\_\_\_ Date \_\_\_\_\_