



INTERNATIONAL HAIR TRANSPLANT INSTITUTE

1070 Powers Place . Alpharetta . GA . 30004 Phone: 800.368.4247

Propecia Consent Form

Finasteride (Propecia)

Finasteride is an oral medication, manufactured by Merck, which blocks the conversion of testosterone to dihydrotestosterone (DHT), the form of the hormone that causes 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.

The medication causes a significant drop in both scalp and blood levels of DHT. Its effectiveness is felt to be related to both of these factors. In patients taking finasteride 1-mg/day, serum DHT levels decreased by 68.4%. Serum testosterone levels actually increased by 9.1% but remained within the normal range.

Finasteride was originally marketed for use in prostate enlargement in men over 50 (the prostate also has the type II enzyme). This medication, in a 5-mg per day dose, is marketed under the name Proscar. In the treatment of prostate problems, finasteride has produced breast tenderness and breast enlargement. It has also caused impotence and decreased sexual interest in a small number of men taking the drug.

In January 1998 the FDA approved finasteride 1-mg/day (Propecia) for the treatment of male pattern alopecia. The phase III human trials, using the 1-mg dose, involved 1,553 men, ages 18 to 41, with Class II Vertex, III Vertex, IV or V balding patterns, i.e. men with mild to moderate hair loss. After two years, results showed that 83% of the men taking finasteride either kept their hair or grew more. Seventeen percent continued to lose hair on the medication. In the vertex (crown), 31% showed moderate improvement and 5% showed great improvement. In the front, only 4% showed moderate improvement and none showed great improvement.

Hair counts showed a gain of 86 hairs in a one-inch circle at the end of one year. These hairs were significantly larger than the fine, miniaturized hair seen in balding, but it is not clear if they all assumed the full weight and diameter of the patient's original hair. As a comparison, hair transplantation can add significantly more density in a single session, and this number can be increased in subsequent sessions. In addition, transplanted hair has the full weight and diameter of the patient's original hair and, of course, is permanent.

Sexual Dysfunction

Although uncommon, there can be side effects of finasteride at the 1-mg/day dose. These include decreased libido (1.8%), impotence (1.3%), and decreased volume of ejaculate (1.2%). It is important to note that there was a small incidence of these problems in the control group as well. Altogether, 3.8% of men taking finasteride 1mg experienced some form of sexual dysfunction verses 2.1% in men treated with placebo (a sugar pill).



INTERNATIONAL HAIR TRANSPLANT INSTITUTE

1070 Powers Place . Alpharetta . GA . 30004 Phone: 800.368.4247

Propecia Consent Form

Most reported cases of sexual dysfunction occurred soon after the medication was begun, but there have been reports of sexual dysfunction that have occurred at later time points. The sexual side effects were reversible in all men who discontinued therapy and in 58% of those who chose to continue treatment. When the medication was stopped, side effects generally went away within weeks, but occasionally took longer.

If sexual side effects occur, they generally begin well before finasteride has had a chance to have visible effects on hair growth. Therefore, men who experience side effects can discontinue the Propecia at this time without the risk of hair loss due to stopping the medication. It is important to remember that when finasteride (or minoxidil) is discontinued, you only lose the hair that was gained or preserved by the medication, not more. In effect, you return to the level of balding that you would have been if you had never used the drugs in the first place.

Gynecomastia

Adverse reactions related to the breast, including breast tenderness or enlargement (gynecomastia), occurred in 0.4% of men taking finasteride 1-mg (Propecia), but this was no greater than in the control group (those that did not take the medication).

In patients on the 5-mg dose (Proscar), the time of onset of breast enlargement ranged from two weeks to 2½ years. In these patients, 80% showed partial or complete resolution when the drug was stopped, and 20% experienced no change.

The mechanism of breast enlargement (gynecomastia) in patients taking finasteride may be due to its ability to block the conversion of testosterone to DHT. This, in turn, may cause more testosterone to be converted to estrogen, with estrogen then stimulating breast tissue. There have been a few cases of breast cancer in patients on the 5-mg dose, but a causative relationship with finasteride has not been established.

Effects on PSA

Finasteride causes an approximate 1/3 decrease in serum PSA (prostate specific antigen) in normal men (from 0.78ng/ml to 0.52 ng/ml). It may also blunt the rise of PSA levels in patients with prostate enlargement and in patients who have developed prostate cancer.

Since PSA is used as a screening test for the development of prostate cancer (the most common type of non-skin cancer in men), there is a concern that the use of Propecia may interfere with the detection of this disease. It is important that your personal physician is aware that you are taking finasteride so that he can take into account any effects that finasteride may have on your PSA. It is possible that the long-term use of Propecia may actually decrease the incidence of prostate disease, but this has not yet been confirmed in scientific studies.



INTERNATIONAL HAIR TRANSPLANT INSTITUTE

1070 Powers Place . Alpharetta . GA . 30004 Phone: 800.368.4247

Propecia Consent Form

Teratogenicity in Females

Finasteride is contraindicated for use in women of childbearing age since birth defects in males can occur if significant amounts of the drug are absorbed into the body during fetal development. It is advised that crushed tablets not be handled by pregnant women out of concern that they may cause harm to the male fetus. However, to our knowledge, there has not been a single reported case of birth defects caused by women handling broken or crushed finasteride tablets. The concern of handling crushed tablets seems to revolve around the FDA policy of assuming maximal possible absorption of the full concentration of the medication during any contact.

There is no evidence that exposure to pregnant women through semen is a risk to the human fetus, but for those patients who wish to limit any potential contact of finasteride to their partner during pregnancy, a condom can be worn once conception has occurred.

Use in Post-Menopausal Women

Merck recently carried out a study to evaluate the efficacy of finasteride in post-menopausal women. After one year there was no significant hair growth and, as a result, the study was terminated. It is possible that the low DHT levels observed in postmenopausal women are responsible for the lack of significant response to finasteride. The safety profile for the use of finasteride in post-menopausal women has not been established.

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 areas that are completely bald. 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, which are thin. The long-term ability of finasteride to maintain one's hair is unknown. Results generally peak around one year and then are stable in the second year or decrease very slightly.

The benefits of finasteride will stop if the medication is discontinued. Over the 2-6 months following discontinuation, the hair loss pattern will generally return to the state that it would have been if the medication had never been used.

It is important to understand that FDA approval of a medication does not mean that all the long-term risks are known. The small, but nevertheless real, incidence of adverse reactions seen with finasteride underscores the fact that its actions are not entirely specific. Only long-term experience with the medication will be able to determine all of its potential effects.



INTERNATIONAL HAIR TRANSPLANT INSTITUTE

1070 Powers Place . Alpharetta . GA . 30004 Phone: 800.368.4247

Propecia Consent Form

Propecia and Hair Transplantation

Propecia (finasteride) has shown to be a useful adjunct to surgical hair restoration for a number of reasons.

- Propecia works best 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.
- Propecia can regrow, or stabilize hair loss, in the back part of the scalp where hair transplantation may not always be indicated.
- If Propecia is shown to be safe and effective in the long-term, it will allow the hair restoration surgeon the ability of creating more density in the cosmetically most important areas (such as the front part of the scalp), since keeping reserves for future hair loss in other areas will be less of a concern.

Patient Monitoring

Men age 40 or over, should consult their regular physician or urologist before beginning Propecia (finasteride 1mg). For those age 40, or over, and are black and/or have a family history of prostate disease, it is recommended that you be evaluated yearly. If you have no family history of prostate problems and are not black, yearly prostate examinations should begin at age 50. This may include a rectal examination, a baseline PSA, and other tests that your examining physician feels are appropriate.

Please note that these are general guidelines recommended for all men of the appropriate age, regardless of whether or not they use finasteride. Specific recommendations for each patient should be based upon the judgement of his own physician.

Prescriptions

Your first prescription for Propecia will be for a 6-month supply. Renewals will be for one year. If you desire to have a PHTC, INC physician prescribe this medication, there will be an \$85 fee for the initial prescription or renewals. You are encouraged to return to our office for follow-up. At each visit, you will be examined and any new information regarding Propecia and/or other therapies will be communicated to you. You will be responsible for obtaining urology evaluations if appropriate. If you experience any problems or adverse reactions while taking Propecia, please contact us and/or your prescribing physician.

Last Name, First

Signature

Date



INTERNATIONAL HAIR TRANSPLANT INSTITUTE

1070 Powers Place . Alpharetta . GA . 30004 Phone: 800.368.4247

Propecia Consent Form
