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# TOPICAL FINASTERIDE CONSENT FORM

**What is finasteride?**

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 androgenetic alopecia.

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 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 6-9 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 10 years. PROPECIA was developed based on a naturally occurring model found in a population of men with type II 5a-reductase deficiency. In this population, type II 5a-reductase deficiency decreased conversion of testosterone into 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, 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.

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 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.

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. There have also been anecdotal reports of changes in penile sensation and shrinkage of the penis on finasteride.*

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.

**Persistent erectile dysfunction (PED)**

A new study examined a large database of patient records and looked for patients who had used finasteride and dutasteride and who also reported erectile dysfunction, decreased libido. In addition - the authors looked at the proportion of patients experiencing persistent sexual dysfunction or "PED" (defined as erectile dysfunction occurring more than 90 days after stopping the drug).

The main messages of the study were that men using finasteride 1 mg have an approximately a 1 % chance of experiencing persistent erectile dysfunction (PED). About 1 in 3 young men who ultimately do experience erectile dysfunction using finasteride will experience persistent erectile dysfunction - and this can last several years (average 3.7 yrs in the study). The longer one is using these medications the greater the risk of PED.

REFERENCE
Persistent sexual dysfunction in men exposed to the 5 alpha reductase inhibitors finasteride or dutasteride. PeerJ 2017

**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 group.

There is some data that suggests an association between finasteride use and breast cancer although a recent study did not find any such link. However, it is recommended that those taking finasteride do self-breast examinations on a routine basis to check for lumps, tenderness, or nipple discharge.

**Other Adverse Reactions**

Other, uncommon side effects, included hypersensitivity reactions including rash, pruritus, urticaria, swelling of the lips and face, testicular pain, thought and mood changes, including depression.

**Finasteride and Prostate Disease**

The results of an 18-year, 18,000 patient study on prostate cancer prevention, 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 decreases the chances of a false positive result in PSA screening tests and can avoid unnecessary surgery.

The FDA will continue its risk/benefit assessment of using finasteride for the treatment for male pattern hair loss and will update the public when additional information is available.

**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 post-menopausal 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 post-menopausal 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 post-menopausal women has not been established.

**Caution during Pregnancy**

Finasteride use is contraindicated in women when they are, or may be, pregnant due to the risk of developmental abnormalities in a male fetus. 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.

**Generic Finasteride**

Finasteride 5mg (Proscar) is available in a generic formulation. Propecia will not be available generically until the year 2012. For those wanting to take generic finasteride, we recommend buying a pill cutter at the pharmacy and taking 1⁄4 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**

We are often asked if one should increase the dose of Propecia. Although we do increase the dose

under certain circumstances, there is no scientific evidence that increasing the dose will have any additional effects. There are published data demonstrating that 5 mg is no better than 1 mg from controlled clinical trials. In practice, we often 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). When increasing the dose, we generally use generic finasteride 5mg, 1⁄2 pill a day (see Caution during Pregnancy).

**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/she may take this into account when interpreting your PSA results.

**Patient Monitoring**

It is recommended that men aged 50, or over, should inform their regular physicians or urologists that they are taking PROPECIA (finasteride 1mg). It is also recommended that all men aged 50 or over have a routine annual evaluation for prostate disease, regardless of whether or not Propecia is used. For those patients who are black and/or who have a family history of prostate disease, these recommendations would apply beginning at age 40. An evaluation should include a rectal examination, a baseline PSA, and other tests that your examining physician feels are appropriate.

The above are general guidelines recommended for all men of appropriate age, regardless of whether they use Finasteride or not. Specific recommendations for each patient should be based upon the judgment of his own physician.

**Topical Finasteride**

Topical finasteride is not FDA approved and is new to the hair loss treatment world. It is not clear yet how well it works and what exactly is the risk of side effects. It is likely that some men will have the same types of side effects as oral finasteride. However the risk of developing these side effects is expected to be much less.

**Prescriptions**

Your first prescription for PROPECIA (finasteride 1mg) will be for a 12-month supply (a 90-day Propak with 3 refills) or for finasteride 5mg #100 1⁄4 tab a day (a 400 day 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 Patient Monitoring). If you experience any problems or adverse reactions while taking finasteride, please contact Dr Donovan.

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# TOPICAL FINASTERIDE Acknowledgement Consent

At Donovan Medical, it is very important to us that you understand the benefit as well as potential side effects. Please initial beside each of the following to indicate that you have reviewed these issues with Dr. Donovan. **I understand and acknowledge that :**

_____ : I understand that topical finasteride is not FDA approved and its use is therefore off label. I understand that topical finasteride can still be associated with side effects although the risk overall of developing these side effects is felt to be less.

_____ : ORAL Finasteride may provide benefit to 90 % of men including improved hair density in 40 % - 50%. Topical finasteride may benefit but the actual magnitude of benefits are unknown. It is likely much less beneficial that oral finasteride.

_____ : ORAL Finasteride may be associated with mood changes such as depression (approx. 1 % of users) and possibly other symptoms like anxiety and memory problems and 'brain fog'. Topical finasteride could cause these too, at least potentially. The actual risk is unknown.

_____ : Finasteride may be associated with sexual side effects, including decreased libido, impotence and decreased sperm volume (1-2 % of users). Topical finasteride could cause these too, at least potentially. The actual risk is unknown.

_____ : Finasteride may be associated with enlargement of breast tissue ( called gynecomastia). Topical finasteride could cause these too, at least potentially. The actual risk is unknown.

_____ : ORAL Finasteride has rarely been associated with permanent and long lasting sexual dysfunction (impotence and decreased libido) although the exact incidence remains unknown. It may be as high as 1 %. Dr. Donovan has explained to me that a class action law suit was launched in Canada by some men. Topical finasteride could cause these too, at least potentially. The actual risk is unknown.

_____ : ORAL Finasteride has rarely been associated with development of testicular pain, changes in penile sensation and shrinkage of the penis. It is unclear how commonly this occurs. Topical finasteride could cause these too, at least potentially. The actual risk is unknown.

_____ : Finasteride users should not donate blood

_____ : Women of child bearing potential should not handle topical finasteride

_____ : Finasteride users over 50 years of age should have a baseline "PSA test" done before starting

_____ : Should I develop side effects from topical finasteride I am to contact Dr. Donovan

_____ : I have received a copy of this side effect form (page 1-5).

_____ _____

NAME DATE (DAY/MONTH/YEAR)

_____

SIGNATURE

PLEASE SEND MY SCRIPT TO THIS PHARMACY: