**Propecia (finasteride) and Avodart (dutasteride) consent form**

(request for treatment).

This information is principally about the effectiveness of Propecia and any potential side effects. There is a lot of misinformation available on the internet but the information presented below, is what the majority of medical practitioners believe about Propecia.

The take home message is that Propecia will reduce hair loss and even improve the quality of the hair, in the majority of male patients, even after 5 years. It won’t work for everybody (but no drug does).

It is a drug widely prescribed for more than 30 years and has been researched throughout that time.

In the majority of men, they do not suffer any side effects, however, in about 1-2% of men, they do suffer short term side effects which improve without treatment.

There may be some men who very rarely suffer longer term or unexpected side effects (also true for all drugs).

Essentially, all male hair loss patients should consider taking this drug as it is well proven to work but each patient needs to make up their own mind as to whether to take it.

Men who are already very bald are less likely to benefit from Finasteride (because the hair follicles may not be salvageable), whereas men with early thinning in the back and top of the head have a better chance to get good results, once the medication is continued.

**Details.**

Propecia is an oral medication, originally 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.

Propecia is the only licensed medication for hair loss in men. Propecia is the brand name of (finasteride 1mg) which became available in December 1997. It is now also available as generic finasteride 1mg. The same drug, under the brand name Proscar (finasteride 5mg) has been approved for the treatment of prostate enlargement since1992.

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 oestradiol 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-reductase deficiency. In this population, type II 5-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. 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 and probably improves further still up to 5 years.

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.

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. 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.

Post Finasteride Syndrome

This is a catch all phrase for a collection of side effects still suffered by a rare number of men after they had stopped the tablet.

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.

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.

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 1-mg (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), 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. 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 negative result.

It is important that you mention you are taking finasteride to your doctor, particularly if are receiving investigations or medication for prostate disease, as this can influence the results of some of the tests.

**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:

To date, animal studies on pregnant monkeys using intravenous doses as high as 800ng/day (which is up to 120 times the highest estimated exposure of women to Finasteride from the semen of men taking 5mg/day) resulted in no abnormalities whatsoever. Nevertheless, to pre-empt this miniscule theoretical risk and for peace of mind, men who are worried can either stop taking the medication altogether or use condoms to prevent any possible Finasteride exposure during pregnancy.

**Finasteride and Sport**

The World Anti-Doping Agency (WADA) removed Finasteride from its list of banned substances in October 2008. It had originally been added because it was suggested that finasteride could be employed to mask the use of steroids and other drugs. However, this is no longer believed to be the case.Nevertheless, we would still advise you to consult your sport’s governing body before taking Finasteride.

Blood Donation

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

**Generic Finasteride (1mg)**

All of the above information is likely to apply equally to generic finasteride as the branded Propecia. Some doctors have questioned whether the generic versions will be equally effective – although the drug chemically may be the same (if made by a reputable laboratory) the binding agents in the tablet could affect absorption etc. There is no evidence to suggest any differences will be clinically significant however.

**Avodart (dutasteride).**

The information above is also likely to apply to dutasteride which is used off label for hair loss. It works in a similar way to finasteride but is not the same drug and has only been available for clinical use for around 15 years. It appears to have similar risks for side effects but could have its’ own idiosyncratic side effects since it’s not the same chemical.

Dutasteride, a second generation 5-alpha reductase inhibitor, is the first medicine to inhibit both the type 1 and type 2 enzymes responsible for the conversion of testosterone to DHT (dihydrotestosterone), the primary cause of prostate growth. Dutasteride’s dual inhibition reduces levels of DHT by 90% at two weeks and 93% at two years. It has not yet been approved for the treatment of male pattern baldness.

**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 no better than 1 mg in controlled clinical trials. In practice, however, doctors may 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.

Female use

Propecia is not licensed for female hair loss and will not benefit most women and could have serious side effects (see pregnancy). However, certain types of hair loss in women can be helped by finasteride but this is a specialist area and finasteride would not routinely be prescribed.

I acknowledge that the doctor has the discussed with me the use and potential side effects of finasteride (Propecia) and that all of my questions have been answered. I acknowledge receipt of the finasteride information sheet.

Please print:

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Written 01/09/2016