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FINASTERIDE (PROPECIA, PROSCAR) SIDE EFFECT & CONSENT FORM

What is finasteride?

- Finasteride is an oral medication (ie. a pill), that inhibits the conversion of testosterone to dihydrotestosterone (DHT). DHT is hormone largely responsible for male pattern baldness (sometimes called androgenetic alopecia).
- Finasteride blocks DHT 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.
- Most individuals who use finasteride have a rapid decrease in serum DHT concentration.
- Reducing the DHT concentration stops or slows the miniaturization (shrinking) of affected hair follicles in many men and helps restore miniaturized hair follicles to regrow visible hair.
- Studies have shown that Circulating levels of testosterone and estradiol are increased by approximately 15% as compared to baseline in the first year of treatment, but these levels were still within normal range. The increase in estrogen is important as some men may experience enlargement of breast tissue on account of this increase.

How good is finasteride in treating hair loss?

- Research has demonstrated that after five years of treatment, 90% of men taking finasteride maintained their hair density or actually improved it.
- At five years, 48% of men treated with finasteride had 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 improvement in hair growth, 19% were rated as having no change and 75% were rated as having lost hair when compared to baseline. In other words, individuals using the placebo had more hair loss
- 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 tiny, miniaturized follicles that are typical of male balding.
- In the "Hair Weight Clinical Study, a 34% mean hair mass/weight difference was observed between finasteride and placebo groups at 96 weeks.

Effectiveness on the Front of the Scalp

- Finasteride also helps treat hair loss in the front part of the scalp. There are published studies demonstrating improvement in a controlled clinical trial of men with frontal hair loss as well.
- In general, finasteride works 'better' on the crown (back of the scalp) but it still can help the front

Long-Term Benefits and Risks

- The effects of finasteride are confined mainly to areas of the scalp that are thinning. There must be hairs present in order for finasteride to benefit that particular area.
- Finasteride does not 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 about 2-3 years. Thereafter finasteride continues to be effective for at least 5 years in slowing down, or preventing additional hair loss. After that some men do experience hair loss again but the important point is that it is at a much much slower rate than if they did not use the medication in the first place. Even after 10 years, men using finasteride have much more hair on their scalp on average than men who did not use.
- The benefits of finasteride will stop if the drug is stopped. Therefore, this is a lifetime treatment. 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 since 1992 when it was approved for prostate problems and 1997 when it was approved for hair loss.

PROPECIA and Hair Transplantation

- Finasteride can be a helpful treatment in combination with surgical hair restoration.
- Finasteride, as described above helps maintains hair or increases hair growth in 90% of patients. The drug works well in the younger patient who may not yet be a candidate for hair transplant surgery.
- Finasteride is somewhat less effective in the front part of the scalp, the area where hair transplant surgery 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 (ie before age 35-40).
- In the long-term, finasteride users who undergo surgery may have better cosmetic outcomes. The use of finasteride may may allow the hair transplant surgeon to create more density in the most cosmetically critical areas (such as the front part of the scalp). This helps to keep reserves for future hair loss in other areas will be of less concern.

Using Finasteride on a Day to Day Basis

- Finasteride is an oral medication that should be taken once daily with or without meals.
- Patients must take Finasteride for one year or longer before they can see the effects (and whether or not they will achieve grow, stabilization or no results at all).
- During the first few months, some patients do experience thinning of their existing hair. A full assessment can help determine why this is occurring for any given patient. For some people, the thinning occurs due to either progression of the balding process before finasteride has had a chance to start working or the finasteride may actually trigger shedding of miniaturized hairs so that new thicker hairs can begin to grow.
- All in all, one really needs to wait 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 but certainly can occur. Any male considering finasteride needs to have a good understanding of the side effect profile and only use if they accept the low chance of side effects
- In general, the one- year chance of drug related side effects is about 1-2 %. Overall, original studies showed that about 3.8% of men taking finasteride 1mg experienced some form of sexual dysfunction verses 2.1% in men treated with a placebo. Sexual dysfunction includes decreased libido, erectile dysfunction, and decreased volume of ejaculate. Other issues may be possible including penile shrinkage, decreased sensation. How common these actually are still needs study
- 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.
- In fact, even if one does not develop sexual problems in the first year of use, it is still possible to experience these problems. In the original clinical studies, the sexual side effects were reversed in those who discontinued therapy, and were even reversed 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.*
- *As stated above, 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.

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

Drug Interactions

- All patients should inform Dr. Donovan if they use any other medications or supplements.
- No drug interactions of clinical importance have been identified although some supplements used in bodybuilding may require finasteride dose adjustment.

Effects on Breast Tissue

- Enlargement of breast tissue can occur with finasteride. This is called gynecomastia.
- There is some data that suggests an association between finasteride use and breast cancer although two very good recent studies 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.
- Psychological and psychiatric issues can occur including thought and mood changes. Depression and anxiety are possible and caution is needed in any patient who has depression and anxiety before starting the medication.
- Changes in blood counts (especially reduced platelets) and increases in muscle enzymes and rarely muscle injury can occur.

Finasteride and Prostate Disease

- It is clear that finasteride reduces the chance of being diagnosed with prostate cancer.
- There has and continues to be some controversy as to whether finasteride increases the risk of high grade prostate cancer.
- The results of an 18-year, 18,000 patient study on [prostate cancer prevention](#), published in the New England Journal of Medicine back in 2013, showed that taking finasteride 5mg a day does not increase the likelihood of dying from prostate cancer. This was some reassurance that even if finasteride did cause some men to have higher grade prostate cancers, it does not affect their longevity.
- 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.

Caution during Pregnancy

- Finasteride use is contraindicated in women when they are pregnant and even if they may become pregnant. This is because finasteride use in women can lead to developmental abnormalities in the baby.
- Female patients should not even handle crushed or broken finasteride 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.
- Users should take note that finasteride pills are coated and will prevent contact with the active ingredient during normal handling, provided that the tablets have not been broken or crushed.
- Despite the much discussion, exposure of pregnant women to semen from men using finasteride has not been shown to pose any risk to the fetus.

Finasteride Use by Men Planning to Start A Family

- This information should be frequently reviewed with Dr. Donovan for updated information as it may change over time as new information emerges. At the present time, there is no evidence that use of finasteride by men increases the risk of birth defects in his children. 1-3 % of all children in the world are born with birth defects and this rate at present seems similar in finasteride users compared to non users. About 1 out of every 100 men who use finasteride while fathering a child will have a baby with a birth defect of some kind - but that rate is similar to men who did not use finasteride.
- **Several agencies currently advise that finasteride not be used by males whose partners are trying to conceive.** Several agencies state that there is no reason for it to be stopped. There is no evidence at present to support either the recommendation not to take or the recommendation to take. [Finasteride: Does it affect spermatogenesis and pregnancy?](#)
- Men with a genetic deficiency of 5 alpha reductase (i.e. men with genetic mutations) may have hypospadias (abnormal opening of urethra), cryptorchidism (undescended testes) and abnormal genitalia. These side effects do not appear increased in men using finasteride based on information available today. Many of these side effects are common in the general population. For example, 3 % of all boys in the world are born with cryptorchidism making it a very common abnormality in the world's population. Similarly 1 in 200 boys are born with hypospadias making it also one of the more common birth defects. In fact, hypospadias is the second most common congenital abnormality after cryptorchidism. We do not have evidence at present to suggest that men using finasteride have a higher than 3 % risk of having a boy with cryptorchidism or higher than a 1:200 risk of hypospadias. At present, all evidence would suggest that 3% of all men who use finasteride would have a baby boy born with cryptorchidism - the same rate as the general population. Similarly, all evidence would suggest that 1 in 200 men who use finasteride would have a baby boy born with hypospadias - the same rate as the general population.
- It's important to be aware that finasteride can lower semen volume in some men. Therefore, men may wish to stop finasteride if there is any issues regarding fertility in the couple. Women, however, must never use finasteride during pregnancy and must never touch crushed tablets.
- Please speak with Dr Donovan about current updates on use of finasteride by men planning to have children.

Generic Finasteride

- Finasteride 5mg (Proscar) and finasteride is available in a generic formulation.
- Some men will choose to split finasteride 5mg pills into four pieces to save money(ie 1.25 mg pieces).
- Although there is no scientific studies to support that this is just as effective, the split pills still provide benefit.
- However, all patients need to be aware that 1 mg pills in some patients do provide better and more consistent results. There are most certainly patients who note worsening hair loss when splitting 5 mg pills and improved hair again when returning to 1 mg again.
- When dividing these tablets, remember that there is a potential risk to pregnant women from handling broken or crushed tablets (see Caution during Pregnancy).

Blood Donation

- Patients taking finasteride can not donate blood as this blood may potentially be given to pregnant women.
- Most blood clinics will routinely ask this question but please do not give blood if you are using finasteride.

Effects on PSA

- Finasteride causes a reduction 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 finasteride so that he/she may take this into account when interpreting your PSA results.
- In essence, once you get your PSA test result back you will need to double the value you see on the paper or screen in order to get your true or 'real' PSA value.

Patient Monitoring

- All men should advise their health care providers that they take any medication including finasteride (finasteride 1mg).
- It is also recommended that all males aged 50 or over have a routine annual evaluation for prostate issues, regardless of whether or not finasteride pills are 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 doctor 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.*

Prescriptions

- In our office, we supply a 1 year prescription of finasteride.
- All patients requiring refills will need to be evaluated again. Dr. Donovan needs to make sure you are tolerating the medication and that it is actually working.
- Please note that we will not simply refill medications without an evaluation. For your safety, such monitoring is essential.
- You will be responsible for obtaining urology evaluations if appropriate (ie PSA and prostate exams if over 50).
- If you experience any problems or adverse reactions while taking finasteride, please contact Dr Donovan. This is a requirement of all users.

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Finasteride (PROPECIA®) Acknowledgement Consent – PAGE 1

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 :**

- _____ : Finasteride may provide benefit to 90 % of men including improved hair density in 40 % - 50%
- _____ : 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’
- _____ : Finasteride may be associated with sexual side effects, including decreased libido, impotence and decreased sperm volume (1-2 % of users).
- _____ : Finasteride may be associated with enlargement of breast tissue (called gynecomastia).
- _____ : Finasteride may be associated with weight gain in some users.
- _____ : 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 high as 1 %.
- Dr. Donovan has explained to me that a class action law suit was launched in Canada by some men.
- _____ : 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.
- _____ : I understand that finasteride use by men planning to father a child has not been conclusively associated with an increased risk of birth defects. However, I understand that studies over time may further define any associated risks to a developing baby. I understand I may reduce any associated risks by choosing to stop my finasteride 1-2 months prior to my partner becoming pregnant and remaining off the medication during the early part of her pregnancy. I understand that it is important to review the latest research with my physicians yearly and prior to my partner becoming pregnant.

Finasteride (PROPECIA®) Acknowledgement Consent – PAGE 2

_____ : Finasteride users should not donate blood

_____ : Women of child bearing potential should not handle broken (crushed) finasteride tablets

_____ : Finasteride users should do regular breast exams to check for lump. I understand that at present there is no definitive evidence to link finasteride with breast cancer.

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

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

_____ : I have received a copy of this side effect form (page 1-6).

NAME

DATE (DAY/MONTH/YEAR)

SIGNATURE

PLEASE SEND MY SCRIPT TO:
