Topical Finasteride

Topical finasteride is a solution containing the drug finasteride — typically sold under the brand names Propecia and Proscar. The Finasteride has been mixed in a liquid formulation that allows it to be applied locally to the scalp area.

In its original form, Finasteride has been approved by the FDA for the treatment of male pattern hair loss and prostate enlargement. The topical formulation, however, has not yet been approved - as it is currently considered by the FDA to be a new drug. As such, it is not yet possible to market the medication commercially, and it must be prescribed on an individual-patient basis. It will be compounded by a pharmacy legally licensed to change the form of the drug based on a physician’s prescription.

Finasteride constitutes the active ingredient in both the topical and oral formulations of the drug. Topical Finasteride has been specifically formulated to function by means of local application to the scalp. It has been designed to significantly reduce the body’s direct exposure to the drug — and thus minimize any potentially adverse effects that may arise from such exposure.

However, it is important to note that it does not entirely eliminate exposure to the drug. While the design of the topical formulation substantially reduces the amount of the drug introduced into the bloodstream, it is still possible to experience the side-effects associated with the oral administration of the drug. That is to say, the absence of adverse effects upon the administration of the drug can in no way be guaranteed.

It is crucial that any person considering the use of topical finasteride fully understand the following information:

What is finasteride?

- Finasteride is a medication (administered either orally or topically), 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 experience a decrease in serum and scalp 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 - allowing for the
regrowth of visible healthy hair.
- Studies have shown that circulating levels of testosterone and estradiol may increase in the first year of treatment - although these levels are usually still within normal range. The increase in estrogen is an important factor to consider - as some men may experience enlargement of breast tissue on account of this increase.

**Effectiveness on the Front of the Scalp**

- Topical finasteride also assists in the treatment of 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, topical finasteride tends to be more effective on the crown (back of the scalp), but still may have an impact on the front.

**Long-Term Benefits and Risks**

- The effects of topical 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 usually cause hair to grow in completely bald areas – although in some cases, improvements have been noted.
- Therefore, the major benefit of finasteride seems to be in its ability to slow down or halt hair loss, as well as 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 – after which some men begin to experience hair loss again. However, it is typically at a much slower rate than if they did not use the medication in the first place. Even after 10 years, men using finasteride typically have much more hair than men who do not.
- The benefits of finasteride will cease if the drug is stopped. Therefore, this is a lifetime commitment. Over 6-9 months following discontinuation of the treatment, the hair loss pattern will generally return to a state similar to that if the medication had never been used.
- Oral Finasteride has been in clinical use since 1992, when it was approved for the treatment of prostate problems. The drug has been used for the treatment of hair loss since 1997.

**Topical Finasteride and Hair Transplantation**

- Finasteride can be a helpful treatment in combination with surgical hair restoration.
- Finasteride, as described above, assists in the maintenance of hair, and has been shown to increase hair growth in 90% of patients. The drug works well in younger patients who may not yet be candidates 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 (i.e. before age 35-40).
- In the long-term, finasteride users who undergo surgery may have better cosmetic outcomes. The use of finasteride 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 means that the preservation of reserves for future hair loss will be of less concern.
Using Topical Finasteride on a Day to Day Basis

- Topical finasteride is a liquid medication that should be applied to the thinning area of the scalp once daily.
- While topical finasteride typically yields results within two months, patients may potentially need to use the medication for one year or longer before seeing improvements. It can then be determined whether they will achieve growth, stabilization or no improvements 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 the progression of the balding process before finasteride has had a chance to start working. In other cases, the finasteride may trigger shedding of miniaturized hairs so that new thicker hairs can begin to grow.
- In summary, a given patient typically needs to wait at least one year before the full benefits can be accurately assessed.

Side Effects

Side effects from the use of topical finasteride at the prescribed dose are very uncommon, but can occur. Any male considering the use of finasteride needs to have a good understanding of the side-effect profile, and only use it if they accept the potential risks involved.

What follows is a description of the most common side-effects associated with oral finasteride. Although topical finasteride is specially formulated to reduce systemic absorption (and therefore reduce the chances of side-effects), the following side-effects associated with oral finasteride could potentially manifest with the use of the topical formulation:

Sexual Dysfunction

- The most common side-effect of the use of finasteride is sexual dysfunction. Sexual dysfunction includes decreased libido, erectile dysfunction and decreased volume of ejaculate. Other issues may be possible including penile shrinkage and decreased sensation.
- 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.

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 reported erectile dysfunction and 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 findings 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 younger 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 uses this medication, the greater the risk of PED.

It is important to note that if 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.

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

Drug Interactions
- All patients should inform their physicians 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 further studies have failed to corroborate this 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 advised for any patient who has experienced depression and/or 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 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

- Exposure to topical finasteride – either direct or indirect – is contraindicated in women when they are pregnant or potentially pregnant. This is because finasteride use in women can lead to developmental abnormalities in the fetus.
- Female patients should ensure that they do not come into contact with topical finasteride when they are pregnant (or potentially pregnant) due to the possibility of absorption of finasteride and the subsequent potential risk to a male fetus. In such cases, it is highly recommended that the male partner stop using topical finasteride for the duration of the pregnancy.
- The exposure of pregnant women to semen from men using finasteride has not been shown to pose any risk to the fetus.

Blood Donation

- Patients using topical finasteride may 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 attempt to give blood if you are using topical finasteride.

Effects on PSA

- Topical Finasteride may cause a reduction in serum PSA (prostate specific antigen) in 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 using finasteride so that he/she may take this into account when interpreting your PSA results.

Patient Monitoring

- All men should advise their health care providers that they are using topical finasteride.
- 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 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 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.
- If you experience any adverse reactions to the medication, you should contact your physician immediately.
Acknowledgement & Consent

Please initial beside each of the following to indicate that you have reviewed and fully understand the following information.

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, 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 been associated with permanent and long lasting sexual dysfunction - although the exact incidence remains unknown. It may be as high as 1%.

_____: There have been class-action law suits surrounding the medication in both the USA and Canada.

_____: 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.

_____: Finasteride users should not donate blood

_____: Women of child bearing potential should not come into contact with topical finasteride

_____: 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 beginning treatment

_____: Should I develop side effects from topical finasteride, I am to contact my physician immediately

_____: I have received a copy of this information form (page 1-6).
I understand that this medication contains the drug finasteride. Any complications that could arise from taking the oral drug could possibly from using the medication topically. I understand that this topical formulation only reduces my exposure to finasteride, and does not eliminate it entirely. I understand that it is my responsibility to ensure that no pregnant woman comes into contact with the medication. I have read and understood the information contained within this document.

I hereby release Drs. Victor Hasson and Jerry Wong, their company, employees and any contractors from any and all liabilities associated with the use of topical finasteride.

______________________________  ______________________________
NAME  DATE (DAY/MONTH/YEAR)

______________________________
SIGNATURE

PLEASE SEND MY SCRIPT TO: