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DUTASTERIDE (AVODART) SIDE EFFECT & CONSENT FORM

What is Dutasteride?

- Dutasteride 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).
- Dutasteride 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 Dutasteride have a rapid decrease in serum DHT concentration. Dutasteride is more effective at reducing DHT than finasteride and is more effective in treating hair loss
- 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 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 Dutasteride in treating hair loss?

- Research has demonstrated that dutasteride is more effective than finasteride. About one-half of users are expected to improve their hair density and another one half are expected to maintain their current density of an extended period of time.

Effectiveness on the Front of the Scalp

- Dutasteride also helps treat hair loss in the front part of the scalp.

Long-Term Benefits and Risks

The effects of Dutasteride 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 Dutasteride 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 Dutasteride peak at one to two years.

Dutasteride continues to be effective for at least 5 years in slowing down, or preventing additional hair loss.

The benefits of Dutasteride 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.

Dutasteride and Hair Transplantation

DUTASTERIDE 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. DUTASTERIDE works well in the younger patient who may not yet be a candidate for hair transplantation. DUTASTERIDE 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, Dutasteride 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 DUTASTERIDE

DUTASTERIDE is an oral medication that should be taken once daily with or without meals. Patients must take Dutasteride for one year or longer before its effects in preventing hair loss and re-growing hair can be accurately assessed. Dutasteride 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 Dutasteride 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 Dutasteride at the 0.5-mg dose may occur in up to 5-17 % of users. Some studies have suggested that side effects occur at a similar rate to placebo and some studies have suggested that the chance of side effects is similar to finasteride. Other studies have suggested that the chance of side effects is a bit higher than finasteride.

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 use of 5 alpha reductase inhibitors. There have also been anecdotal reports of changes in penile sensation and shrinkage of the penis on 5 alpha reductase inhibitors. While these studies have largely to date been with finasteride (Propecia), one can exclude the possibility that these side effects can also occur with dutasteride.*

When Dutasteride 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 body of literature has looked at sexual dysfunction with finasteride. We do not know how and if this correlates to dutasteride use but for now we must assume it is highly relevant and side effects of finasteride apply to dutasteride equally well.

A new study examined a large database of patient records and looked for patients who had used finasteride 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 Dutasteride or dutasteride. PeerJ 2017

Effects on Breast Tissue

Adverse reactions related to the breast, including breast tenderness or breast enlargement (gynecomastia), occurred in men taking Dutasteride. Overall the risk of gynecomastia is known to be slightly greater with dutasteride than finasteride.

There is some data that suggests an association between 5 alpha reductase inhibitor use and breast cancer although a recent study did not find any such link. However, it is recommended that those taking Dutasteride 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.

Dutasteride 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 5 alpha reductase inhibitors 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, Dutasteride 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 Dutasteride for the treatment for prostate issues and will update the public when additional information is available. For now, it seems that dusteride reduces the risk of prostate cancer.

Off-Label Use of Dutasteride in Women

Although Dutasteride is being prescribed for the treatment of female pattern hair loss (androgenetic alopecia) and frontal fibrosing alopecia in POST-MENOPAUSAL WOMEN, it is not FDA approved for use in women. As such, the safety profile for the use of Dutasteride 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.

Dutasteride should not be used by women without expert evaluation by a physician who is knowledgeable and experienced in the diagnosis and management of complex hair disorders.

Caution during Pregnancy

Dutasteride 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 DUTASTERIDE tablets when they are pregnant, or may potentially be pregnant, because of the possibilities of absorption of Dutasteride and the subsequent potential risk to a male fetus. DUTASTERIDE 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 DUTASTERIDE has not been shown to pose any risk to the fetus. All men using dutasteride should speak to Dr. Donovan if they plan to father a child.

Blood Donation

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

Effects on PSA

Dutasteride 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 Dutasteride (Dutasteride) 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 DUTASTERIDE (Dutasteride 0.5 mg). It is also recommended that all men aged 50 or over have a routine annual evaluation for prostate disease, regardless of whether or not Dutasteride 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 Dutasteride or not. Specific recommendations for each patient should be based upon the judgment of his own physician.

Prescriptions

Your first prescription for DUTASTERIDE (Dutasteride 0.5 mg) will be for a 12-month supply. At each visit, you will be examined and any new information regarding Dutasteride 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 Dutasteride, you MUST contact Dr Donovan.

Dutasteride (DUTASTERIDE®) 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 :**

_____ : Dutasteride may provide benefit to 90 % of men including improved hair density in 40 % - 50%

_____ : Dutasteride 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'

_____ : Dutasteride may be associated with sexual side effects, including decreased libido, impotence and decreased sperm volume (1-2 % of users).

_____ : Dutasteride may be associated with enlargement of breast tissue (called gynecomastia) in about 15 to 30 out of every 1000 users of the drug. This is more common of an occurrence than finasteride.

_____ : Finasteride has rarely been associated with permanent and long lasting sexual dysfunction and we must assume for now that there is a chance this could occur with dutasteride. (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 pertaining to the drug finasteride.

_____ : Dutasteride 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.

_____ : Dutasteride users should not donate blood

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

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

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

_____ : Should I develop side effects from Dutasteride 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: