

## A Word of Caution on Avodart

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### Consumer Alerts

Side effects with Avodart for hair loss may be an issue, so be careful. Dr. Edwin Epstein conveys his concerns with the recent type about Avodart for the off-label treatment of hair loss, in this editorial piece written from the viewpoint of the prescribing physician....

### **Propecia vs. Avodart: Know the facts**

There is a lot of interest in the use of Avodart (active ingredient: Dutasteride) as an off-label medication for the treatment of hair loss. Since Dutasteride is only approved to treat benign enlargement of the prostate, the off-label use to treat hair loss should be approached cautiously. Dutasteride is marketed as Avodart by Glaxo Smith Kline at a dosage of 0.5mg. It is in gel capsule form, so cutting it up will be difficult, and must be kept in a cool place so they will not stick together. It costs \$75-95 for a 1 month supply at 0.5mg.

I have prescribed Propecia since its FDA approval in 1997 to over 1000 patients, and have used it myself for over 3 years without side effects. I believe that knowing the risks and benefits of a medication is essential to deciding whether or not it is the right choice for the treatment of condition in question.

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### **Dr. Edwin S. Epstein**

Dr. Epstein has specialized in hair restoration surgery since 1990 and is Virginia's only surgeon Board Certified in Hair Restoration Surgery. He founded the Stuart Medical Group in 1994, and is both medical director and owner. He graduated Duke in 1972 and received his medical degree from Georgetown in 1977. He is Board Certified by the American Board of Hair Restoration Surgery, and the American Board of Urology.

Dr. Epstein's website: <http://www.stuartmed.com>

Let's compare some of the differences between Propecia (finasteride) and Avodart (dutasteride):

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### **Method of Action**

Both block the formation of DHT from Testosterone, by inhibiting the enzyme 5-alpha reductase. Unlike Propecia (Merck) which inhibits the 5 AR-2 enzyme only, Avodart (Glaxo Smith Kline) inhibits both 5AR-2 and 5AR-1 enzymes.

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### **Biological Model**

Finasteride has a biological model and dutasteride does not. This quite simply means that there is much more safety data on Propecia than Avodart right now. The effects of 5AR type 2 deficiency, (the same environment Propecia creates) have been thoroughly studied for over 25 years in a group of patients in the Dominican Republic. The long-term "side effects" are no hair loss, and no prostate cancer. Patients with genetic 5AR-2 deficiency have no life-threatening disorders and there is no 5AR-2 present in their brain tissue. Conversely, there is no biological model for 5AR type 1 deficiency, which Avodart creates, and there are measurable levels of 5AR-1 in the human brain. Conclusion -- the blockage of 5AR-1 may have yet unknown neurological implications.

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### **Dosage**

Glaxo presented the results from the Phase II studies about 3 yrs. ago in a closed session only to the investigators involved in the study. From what was presented, the dutasteride side effects were very similar to the finasteride side effects (5 mg) tested dose. Dutasteride's sexual side effects were in the range of 3-4% versus 1-2% for finasteride 1mg (Propecia) and 3-4% for finasteride 5mg (Proscar). The results of the phase II trials did show that 2.5 mg of Avodart gave nearly 2-3 times more hair growth than finasteride did at a full 5 mg, resulting even in frontal hair growth in some men. However, these superior results were at a rather high 2.5mg dosage. Both Finasteride and Dutasteride have originated as Prostate medications, but Dutasteride's prostate dose is actually lower than the tested dose for hair loss. Glaxo seems to be doing the exact opposite of Merck in this sense. Finasteride worked better on the prostate at the higher dose (5mg - Proscar), and for hair at a lower dose (1mg - Propecia). Dutasteride was released for the prostate at the lower dose (Avodart - 0.5mg), and was tested with results on hair loss at 5 times the dose (2.5mg). The higher the dose, the more potential for side effects.

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### **Duration of Side Effects**

The greatest concern however, is the potential *duration* of side effects. The long half life of dutasteride exceeds 240 hours vs. the rather short 6 to 8 hours for finasteride. There have been some cases where the DHT levels were still had only returned to 25% of their original levels nearly a YEAR after having discontinued Dutasteride. As a result, any dangers or side effects that may be seen from Avodart, whether directly related or as a hypersensitive or allergic reaction may take literally months to resolve.

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### **Cost**

Using dutasteride at the 2.5 mg dose will be quite expensive. Since many people are considering taking the 2.5mg dose, and Avodart is sold in 0.5mg capsules at nearly \$90 for 30, basic math reveals quite a hefty monthly expense for this off-label treatment.

orangearrowtrans.gif **Dosing  
Frequency**

On the other hand, the good news is that due to the long duration of action, the optimal dosage frequency might be once weekly or even once monthly. However, the fact remains that there is no clinical data to look towards regarding less frequent dosage schedules, so we doctors, and our patients, will be on our own. The ideal patient may be the person who has used Propecia for extended periods of time and saw results with no side effects.

orangearrowtrans.gif **Perspective?**

I find that many patients are reluctant to take Propecia because of the sexual side effect disclaimers from the original TV ads by Merck. As a result, I find this irrational fervor to take Avodart worrisome, because we do not know about long-term side effects, nor how long the short-term side effects, if experienced, will last.

**Conclusion**

True, the preliminary results for hair growth are encouraging, but at what price? Glaxo has not done even presented the bare minimum needed as far as safety or dosing data for this drug to be used to treat hair loss. The most effective dose that carries the least chance of side effects. This is what Merck did for us with Propecia, and the data backing their recommendation is imperative to have. Perhaps the initial, ideal Dutasteride patient will be the one having had no problems with Propecia, who wants to improve their results. However, Dutasteride stays in the body for months, and maybe as long as a year. So if complications arise from its use, they will be around for a long time. Remember Fen-Fen for weight loss? Personally, I do not want my patients to be the guinea pigs.

Edwin S. Epstein, MD

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