THE PACKAGE INSERT SERIES

Finasteride and Dutasteride — The Hair Loss Drugs Whose Sexual Side Effects May Not Stop When the Drug Does

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The Propecia label lists post-marketing reports of "sexual dysfunction that continued after discontinuation of treatment, including erectile dysfunction, libido disorders, ejaculation disorders, and orgasm disorders; male infertility and/or poor seminal quality." This is a drug prescribed to otherwise healthy men in their twenties and thirties for cosmetic purposes. Its own label acknowledges that the sexual side effects may not stop when the drug does.

> *That is one sentence from one section of one label. Across both drugs in this class, the prescribing information documents a pattern most patients never see: finasteride crosses the blood-brain barrier, dutasteride remains detectable in the blood for four to six months after the last dose, both drugs can feminise the genitalia of a male fetus through skin contact alone, both carry warnings about increased rates of high-grade prostate cancer, and both admit that the relationship between long-term use and male breast cancer is "currently unknown". These are statements from the FDA-approved labels, written by the manufacturers and filed with the agency.*

This installment covers the only two drugs in the 5-alpha reductase inhibitor class: finasteride (Propecia, 1 mg — approved 1992) and dutasteride (Avodart, 0.5 mg — approved 2001). Finasteride is FDA-approved for male pattern hair loss. Dutasteride is not — it is approved only for benign prostatic hyperplasia — yet it is routinely prescribed off-label for the same purpose. What follows is what their labels say.

One phrase in the Propecia label's mechanism of action section sets the terms for everything that follows. The label states that finasteride works "in those patients genetically predisposed" to androgenetic alopecia. That phrase does more than describe the drug's target population — it defines the problem so that pharmaceutical intervention is the only available answer. If hair loss is genetic destiny mediated by a hormone, then suppressing that hormone with a daily pill is the logical — and only — response. Whether hair loss might reflect toxic burden, nutritional deficiency, or endocrine disruption from environmental sources is a question the label's framing does not permit. The assumption sits in the mechanism section, presented as settled science, never examined. For readers who want to look at the genetic predisposition framework itself — what the evidence actually supports and what it forecloses — I have written separately on that subject: *Genetics: The Ultimate Cover Story*.

The Package Insert reads the FDA-approved prescribing information for major drug classes in each installment and reports what the labels actually say — including what they admit has not been studied. If you're currently taking a 5-alpha reductase inhibitor, considering one, or have a family member on one, this is the installment to start with.

What the Labels Say These Drugs Do

Finasteride and dutasteride belong to the same drug class, but they are not the same drug. Finasteride inhibits only the Type II isoform of the enzyme 5-alpha reductase. Dutasteride inhibits both Type I and Type II. The distinction matters: Type II is primarily active in reproductive tissues and hair follicles, while Type I operates in the skin and liver. By blocking both isoforms, dutasteride suppresses circulating DHT by approximately 90–95% at steady state. Finasteride suppresses it by about 65%.

Both drugs raise circulating testosterone — finasteride by approximately 15%, dutasteride by 19–26% depending on duration of use. Both also raise oestradiol. The Propecia label states these increases "remained within the physiologic range". The Avodart label documents a statistically significant increase in thyroid-stimulating hormone at 52 weeks that returned to baseline after stopping the drug.

The clinical evidence for hair regrowth comes entirely from the finasteride label. Propecia's pivotal trials enrolled men aged 18 to 41 with mild to moderate hair loss — 88% Caucasian. All participants, including those on placebo, were instructed to use a medicated tar-based shampoo (Neutrogena T/Gel) during the first two years. The trials measured hair count within a one-inch diameter circle on the scalp. At 12 months, finasteride-treated men had 107 more hairs than placebo in that circle. At five years, the difference was 277 hairs — but by that point the placebo comparison group had dwindled to 15 men, down from 672 at the start.

The efficacy data gets worse over time. Maximum hair count improvement was achieved during the first two years, followed by "a slow decline". At five years, 35% of finasteride-treated men had still lost hair compared with baseline. The drug slowed the loss; it did not stop it. And it did not work everywhere. The label states that "efficacy in bitemporal recession has not been established" — the receding hairline that most men notice first is the pattern the drug was never shown to address.

The label also contains a study in women. In 137 postmenopausal women with androgenetic alopecia treated for 12 months, "effectiveness could not be demonstrated". No improvement in hair counts, self-assessment, investigator assessment or photographs. The drug does not work for women — and it is contraindicated in women who may become pregnant.

Dutasteride has no hair loss data in its label at all. Avodart is approved exclusively for symptomatic benign prostatic hyperplasia in men with an enlarged prostate. Its trials enrolled men aged 47 to 94 — a population that bears no resemblance to the young men receiving it off-label for alopecia. The label's clinical studies section documents symptom scores, urinary retention, prostate volume and urine flow rates. Hair is not mentioned once. The drug that was tested for hair loss doesn't work in half the population. The drug that was never tested for hair loss is prescribed for it anyway.

When a physician prescribes dutasteride for hair loss, the safety information that applies — the side effect rates, the drug interactions, the warnings — comes from trials in elderly men with prostate disease. The label was written for them. The off-label patient is borrowing someone else's risk profile.

> ASK YOUR DOCTOR
> *Was this drug studied in men my age for hair loss, or are the safety data from a different population?*

Sexual Side Effects and the Persistence Problem

Both labels document the same core sexual adverse effects: decreased libido, erectile dysfunction and ejaculation disorders. In Propecia's 12-month hair loss trials, these occurred at low single-digit percentages — 1.8% for decreased libido (versus 1.3% placebo), 1.3% for erectile dysfunction (versus 0.7% placebo), 1.2% for ejaculation disorder (versus 0.7% placebo). The integrated analysis found 3.8% of finasteride-treated men reported at least one of these effects, compared with 2.1% on placebo.

The clinical trial numbers are not the whole picture. Under post-marketing experience — the section documenting what emerged after approval, from voluntary reports — the Propecia label lists the persistence language quoted at the top of this article: sexual dysfunction that continued after discontinuation, including erectile dysfunction, libido disorders, ejaculation disorders and orgasm disorders. It also lists male infertility and poor seminal quality.

The Avodart label says it differently. A footnote attached to the sexual adverse reaction tables reads: “These sexual adverse reactions are associated with dutasteride treatment (including monotherapy and combination with tamsulosin). These adverse reactions may persist after treatment discontinuation. The role of dutasteride in this persistence is unknown.”

That final sentence appears twice in the Avodart label, verbatim, attached to two separate adverse reaction tables. The manufacturer is saying, on the record, that it does not know why the sexual side effects of its drug persist after the drug is stopped.

Buried in the clinical studies section — not the adverse reactions section — is a sexual function questionnaire administered to trial participants. It found “statistically significant differences in favor of placebo” in three of four domains: sexual interest, erections and perception of sexual problems. The label includes this result and then notes that “no significant difference was seen in the question on overall satisfaction with sex life”. The trial's own instrument detected a measurable sexual deficit across three dimensions, fifteen

pages from the adverse reactions table.

Dutasteride's adverse effect rates run higher — though the trial population was older and sicker, so direct comparison with finasteride's hair loss trials is not possible. In the first six months, impotence was reported at 4.7% (versus 1.7% placebo), decreased libido at 3.0% (versus 1.4%), and ejaculation disorders at 1.4% (versus 0.5%). In the CombAT trial, which added tamsulosin, ejaculation disorders hit 7.8% in the combination group.

> ASK YOUR DOCTOR
> *If I develop sexual side effects on this drug, what does the label say about whether they will resolve after I stop taking it?*

The Prostate Cancer Warning

The warning appears on both labels, and neither manufacturer can explain it.

The Prostate Cancer Prevention Trial (PCPT) was a seven-year, randomised, double-blind study that enrolled 18,882 healthy men aged 55 and over. It used finasteride at 5 mg daily — five times the hair loss dose. The Propecia label reports the result: men taking finasteride had a higher incidence of Gleason score 8–10 prostate cancer, 1.8% versus 1.1% on placebo. The REDUCE trial tested dutasteride in 8,231 men aged 50 to 75 over four years. The Avodart label reports: Gleason 8–10 cancer in 1.0% of dutasteride-treated men versus 0.5% on placebo. In both trials, the rate of the most aggressive prostate cancer grade roughly doubled in the treatment group.

The labels share identical hedging language: whether 5-alpha reductase inhibitors increase the risk of high-grade prostate cancer, or whether the effect of reducing prostate volume or study-related factors impacted the results, “has not been established”.

The Avodart label adds: “AVODART is not approved for the prevention of prostate cancer.” The Propecia label states: “No clinical benefit has been demonstrated in patients with prostate cancer treated with PROSCAR.”

These drugs are not approved to prevent prostate cancer, they carry warnings about an association with its most aggressive form, and neither manufacturer can explain the finding. The warning was added to the Propecia label in 2011 — nearly two decades after the drug's approval — as a “Recent Major Change”.

The cancer warning creates a screening problem too. Both drugs reduce prostate-specific antigen levels by approximately 50%. PSA is the standard screening marker for prostate cancer. Both labels warn that any confirmed increase from the lowest PSA value while on the drug “may signal the presence of prostate cancer and should be evaluated, even if PSA

levels are still within the normal range". A drug that halves the value of a cancer screening test while carrying a warning about increased high-grade cancer rates creates a detection gap the labels acknowledge but do not close.

> ASK YOUR DOCTOR
> *Given that this drug reduces my PSA levels and carries a warning about high-grade prostate cancer, how will prostate cancer screening work while I'm on it?*

What the Drugs Do to Sperm and Fertility

The Avodart label contains an entire warnings section titled "Effect on Semen Characteristics". In a study of healthy men taking dutasteride 0.5 mg daily for 52 weeks, the drug reduced total sperm count by 23%, semen volume by 26%, and sperm motility by 18%, compared with placebo. The label then states: "the effects on total sperm count were not reversible after 24 weeks of follow-up."

Twenty-four weeks is six months. Half a year after stopping the drug, sperm counts had not recovered.

The detailed data in the reproductive potential section is more specific. Two of 27 men in the dutasteride group — roughly 7% — "had decreases in sperm count of greater than 90% from baseline at 52 weeks, with partial recovery at the 24-week follow-up". Partial recovery. In a study of a drug prescribed to men of reproductive age.

The label summarises all of this in a single sentence: "The clinical significance of dutasteride's effect on semen characteristics for an individual patient's fertility is not known."

Finasteride's label has less data but a worse post-marketing record. The clinical trials section reports a median decrease in ejaculate volume of 0.3 mL (11%) at the 1 mg hair loss dose and 0.5 mL (25%) at the 5 mg prostate dose. The post-marketing section lists "male infertility and/or poor seminal quality" among adverse reactions reported after approval, with the parenthetical note that "normalization or improvement of seminal quality has been reported after discontinuation of finasteride". The word "reported" is doing work in that sentence — it does not say demonstrated, studied or confirmed.

The animal fertility data is consistent. In male rats treated with finasteride for 24 to 30 weeks, there was "an apparent decrease in fertility, fecundity, and an associated significant decrease in the weights of the seminal vesicles and prostate". Effects were reversible after six weeks. The Propecia label explains the mechanism: finasteride prevented formation of the seminal plug needed for rat fertility, and notes that "the seminal plug is essential for normal fertility in rats but is not relevant in man". The animal finding was dismissed on

anatomical grounds — but the human post-marketing reports of infertility arrived anyway.

Dutasteride's animal fertility data is more extensive. Male rats treated at 0.1 times the maximum recommended human dose showed “dose- and time-dependent decreases in fertility at all doses” along with reduced sperm counts, decreased reproductive organ weights, and microscopic changes in the epididymis, prostate and seminal vesicles. All doses. In the absence of paternal toxicity.

> ASK YOUR DOCTOR
> *What does the label say about the effects of this drug on sperm count and fertility, and how long those effects last after stopping?*

The Fetus Risk Beyond the Patient

Both labels are contraindicated in pregnancy — not because women would take them, but because skin contact with the drug can harm a male fetus. The Propecia label warns that “women should not handle crushed or broken PROPECIA tablets when they are pregnant or may potentially be pregnant because of the possibility of absorption of finasteride”. The Avodart label goes further: dutasteride capsules “should not be handled by women who are pregnant or may be pregnant”, and the drug “can be absorbed through the skin”.

The animal studies show what happens. In pregnant rats given finasteride at doses as low as 0.02 times the recommended human dose, male offspring showed decreased anogenital distance — a marker of feminisation. At higher doses, 3.6% to 100% of male offspring developed hypospadias, a malformation of the urethra. The Avodart label reports feminisation of male rat genitalia at doses 10 times less than the maximum recommended human dose, “with a lack of a no-effect level” — meaning the researchers could not find a dose low enough to avoid the effect.

In rabbits, dutasteride produced feminisation of male fetus genitalia and fused skull bones at all doses tested, again with no no-effect level.

The Avodart label carries a warning found nowhere in the Propecia label: men taking dutasteride “should not donate blood until at least 6 months have passed following their last dose”. The purpose is “to prevent administration of dutasteride to a pregnant female transfusion recipient”. Dutasteride's terminal elimination half-life is approximately five weeks — versus 4.5 to 6 hours for finasteride. The drug remains detectable in serum for four to six months after the last dose. A man who stops dutasteride in January may still carry measurable drug levels in July.

> ASK YOUR DOCTOR
> *If my partner is or may become pregnant, what precautions does the label recommend while I'm on this drug and after I stop?*

Depression, Breast Cancer, and What Crossed the Blood-Brain Barrier

Both labels report depression in their post-marketing sections. The Propecia label lists it under “Nervous System/Psychiatric”. The Avodart label lists “Depressed mood” under “Psychiatric Disorders”. No incidence rates. Post-marketing sections never have them — the data comes from voluntary reports, and as both labels say, “it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure”.

The Propecia label contains one sentence that the Avodart label does not: “Finasteride has been found to cross the blood-brain barrier.” It appears in the pharmacokinetics section, under distribution, between data on protein binding and semen levels. It is not referenced in the warnings, not mentioned in adverse reactions, not discussed in patient counselling. It is there, and it is alone.

Dutasteride's neurological signal comes from animals, not humans. Under “Central Nervous System Toxicology Studies”, the label reports that “in rats and dogs, repeated oral administration of dutasteride resulted in some animals showing signs of non-specific, reversible, centrally-mediated toxicity without associated histopathological changes” at exposures 315- to 425-fold the expected human exposure. The toxicity was “non-specific” and “reversible”. The label does not say what the signs were.

Male breast cancer appears in the post-marketing sections of both labels. The Propecia label details the numbers: four cases of breast cancer in men treated with finasteride 5 mg in the MTOPS study (none in the untreated group), two cases in placebo-treated men in the PLESS study (none in finasteride-treated men), and one case in each group in the PCPT trial. Both labels deliver the same conclusion: “The relationship between long-term use of finasteride [or dutasteride] and male breast neoplasia is currently unknown.” Both labels instruct physicians to tell patients to “promptly report any changes in their breasts such as lumps, pain or nipple discharge”.

The animal carcinogenicity sections carry a testicular signal. In mice given finasteride at 1,824 times the human exposure, researchers observed a statistically significant increase in testicular Leydig cell adenomas. In rats given dutasteride at 135 times the maximum recommended human dose, the same tumour type appeared. Both labels attribute this to a documented mechanism: finasteride and dutasteride elevate luteinising hormone levels (two- to threefold above control in rats), and this hormonal shift drives proliferative

changes in the Leydig cells. The drugs alter the hormonal environment of the testes. The testes develop tumours. The labels explain why they believe the animal doses are not relevant to human use — but neither label contains long-term human testicular data to confirm that belief.

> ASK YOUR DOCTOR
> *The label says finasteride crosses the blood-brain barrier. Was that discussed with me before I started this medication?*

The Cardiac Signal in the Combination Data

The Avodart label carries one warning the Propecia label does not: a cardiac failure signal. In the CombAT trial — which tested dutasteride combined with tamsulosin over four years — the incidence of cardiac failure in the combination group was 0.7% (12 of 1,610 subjects), compared with 0.1% (2 of 1,623) for dutasteride alone and 0.6% (9 of 1,611) for tamsulosin alone. In the separate REDUCE trial, cardiac failure occurred in 0.6% of dutasteride-treated subjects versus 0.4% on placebo.

The label qualifies this three times in three sentences: “A majority of subjects with cardiac failure in both trials had comorbidities associated with an increased risk of cardiac failure. Therefore, the clinical significance of the numerical imbalances in cardiac failure is unknown. No causal relationship between AVODART alone or in combination with tamsulosin and cardiac failure has been established.”

The signal exists. The label documents it. And then it walks it back. The cardiac failure data comes from elderly men with prostatic disease and pre-existing cardiac risk factors — a population that shares nothing with the young men taking this drug for hair loss except the molecule itself.

> ASK YOUR DOCTOR
> *If I am taking dutasteride, does the cardiac failure signal in the Avodart label apply to someone in my age group and health profile?*

What the Labels Admit Has Not Been Studied

Drug labels always have gaps — sections where the answer is “has not been studied” or “is not known”. The question for this drug class is where those gaps fall relative to the people actually taking the drugs.

For 5-alpha reductase inhibitors prescribed to young men for hair loss, the first place to look is long-term reproductive data. Neither label has any. Dutasteride's sperm study ran 52 weeks with 24 weeks of follow-up — and even in that window, the sperm count reductions were not reversible. Finasteride's fertility data is limited to animal studies and post-marketing voluntary reports. The Propecia label recommends “continued use” to sustain benefit and warns that stopping leads to “reversal of effect within 12 months”. The drug is designed to be taken indefinitely. The reproductive consequences of indefinite use have not been studied.

Then there is the liver. Both drugs are extensively metabolised hepatically, and both labels state that the effect of hepatic impairment on their drug's pharmacokinetics “has not been studied”. The Propecia label advises “caution” in patients with liver function abnormalities. The Avodart label notes that “exposure could be higher in hepatically impaired patients” and offers a clinical trial at 10 times the therapeutic dose as indirect reassurance — but that trial did not study impaired livers either.

The Avodart label states directly: “The effect of race on dutasteride pharmacokinetics has not been studied.” Propecia's clinical trials were 88% Caucasian. The ethnic analysis of hair count data included only 84 Black men, 17 Asian men and 45 Hispanic men across the combined trials. Patient self-assessment showed “improvement across racial groups with PROPECIA treatment, except for satisfaction of the frontal hairline and vertex in Black men”. Whether either drug works differently — or produces different side effect profiles — in non-white populations is a question neither label can answer.

The rest is boilerplate, but it adds up. The Avodart label states that the effect of renal impairment on dutasteride pharmacokinetics “has not been studied”, though it dismisses the gap because less than 0.1% of the dose is recovered in urine. The same label states that “the effect of potent CYP3A4 inhibitors on dutasteride has not been studied” — the drug interaction data comes from in vitro studies, not clinical trials. Paediatric safety and effectiveness “have not been established” for either drug, and dutasteride's pharmacokinetics “have not been investigated in subjects younger than 18 years”. The Propecia label notes that its clinical efficacy studies “did not include subjects aged 65 and over”.

Any single gap is defensible. Taken together, they describe a drug class where the target patient — a healthy man in his twenties or thirties, taking medication for cosmetic reasons, not treating a disease — was never the population the labels were written for. The safety data comes from older men with prostate disease. The fertility data is short-term. The liver data does not exist. The racial data is thin. The labels were not built for the patient in the chair.

> ASK YOUR DOCTOR
> *Have any of the gaps in the label's data — hepatic effects, racial differences, long-term fertility — been addressed by studies published since the label was last revised?*

Questions to Take to Your Doctor

These questions are drawn directly from information in the FDA-approved prescribing labels for Propecia (finasteride 1 mg) and Avodart (dutasteride 0.5 mg). They are meant to help you have a more specific conversation with your prescriber.

1. The Propecia label states that sexual dysfunction, including erectile dysfunction and libido disorders, "continued after discontinuation of treatment" in post-marketing reports. What is your experience with patients who develop these side effects — do they resolve?
2. The Avodart label states that the role of dutasteride in the persistence of sexual side effects after stopping the drug "is unknown". If I am being prescribed dutasteride off-label, has this been discussed with me?
3. Both labels carry a warning about increased rates of high-grade prostate cancer (Gleason 8–10). Given that these studies used the drugs for prostate indications, does this warning apply at the lower doses or shorter durations typical of hair loss treatment?
4. Both drugs reduce PSA levels by approximately 50%. How will you adjust my PSA screening while I am on this medication?
5. The Avodart label reports that reductions in total sperm count were "not reversible after 24 weeks of follow-up". Two study participants experienced sperm count decreases greater than 90%. If I plan to have children, what is the recommended washout period?
6. Finasteride's label states that the drug "has been found to cross the blood-brain barrier". Both labels list depression in post-marketing reports. Should I be monitored for mood changes?
7. The Avodart label documents a cardiac failure signal in two separate trials. Does this finding have relevance for someone my age taking the drug for hair loss?
8. The Propecia label states that "efficacy in bitemporal recession has not been established". Is the drug likely to address the specific pattern of hair loss I am experiencing?

9. If I am being prescribed dutasteride for hair loss, is there clinical trial data supporting that use, or is the prescription based on the drug's mechanism of action?
10. Dutasteride has a terminal elimination half-life of approximately five weeks and remains detectable in the blood for four to six months after stopping. What does this mean for managing side effects if they develop?
11. Both labels state that the effect of hepatic impairment on drug pharmacokinetics "has not been studied". Should liver function be monitored during treatment?
12. The Propecia label's clinical trials enrolled men aged 18 to 41 who were 88% Caucasian. If I am outside that demographic, is there data on efficacy and safety in my population?
13. The Propecia label recommends "continued use" to sustain benefit and notes that "withdrawal of treatment leads to reversal of effect within 12 months". What does the label say about the safety of indefinite use?

> Disclaimer
> This article is not medical advice. Its purpose is to help readers read what is written in the FDA-approved prescribing information and to ask better questions of the physicians who prescribe these drugs. Nothing here should be taken as a recommendation to start, stop or change any medication. Those decisions belong to you and your doctor.

Sources

- Propecia (finasteride) tablets, 1 mg — NDA 020788 (Merck Sharp & Dohme Corp.) — Revised 04/2012. Available at FDA.gov/drugsatfda.
- Avodart (dutasteride) capsules, 0.5 mg — NDA 021319 (GlaxoSmithKline) — Revised 01/2020. Available at FDA.gov/drugsatfda.