

Direct-to-consumer advertising *Finasteride for male pattern hair loss*

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Case

Mr Jones (26 years old) comes to see you about a cough he has had for 3 to 4 weeks. You have just finished listening to his chest and reassured him that it is the aftermath of a viral infection. He asks you, "By the way, I'm wondering about this pill I saw advertised. I think the name was Propecia. I've been noticing my hair seems to be thinning on top lately, and I'd like to try it."

Does this sound familiar?

Clinicians are increasingly feeling the effects of direct-to-consumer advertising (DTCA) of prescription drugs. While advertising prescription drugs directly to consumers is not allowed in Canada, patients see newspaper reports, American advertisements, advertisements directed at health professionals, and so on. In Canada, practising physicians can expect to get an average of 10 specific drug requests per week, some of which would be for advertised drugs. In the United States, DTCA appears to increase sales (see sidebar).¹

What should clinicians do in this situation?

Let us explore the issue using one of the products most widely advertised to consumers, a drug for male pattern hair loss, finasteride (eg, Propecia®).

Questions before writing a prescription

Does this patient fit the drug's indications?

Propecia® is for a cosmetic effect in young men (18 to 41 years old) who have mild to moderate hair loss on the vertex or anterior midscalp.² It does not benefit men with hair loss at the temples or those who are completely bald.³ It is not indicated for women or children.^{2,4}

Does the patient have a realistic idea of the drug's effectiveness?

Three papers summarize five randomized controlled trials involving men between the ages of 18 and 41 years.⁵⁻⁷ When finasteride was compared with placebo

using enlarged photographs of 1-inch-diameter circles, hair counts increased by 12% over baseline at 1 year ($P < .001$).⁵ Responses on the patient questionnaire revealed that finasteride improved the appearance of the hair in 58% of patients compared with placebo in 35% (absolute benefit increase [ABI] 23%, 95% confidence interval [CI] 18 to 28, number needed to treat [NNT] four for 1 year).

Overall, 39% of the finasteride group were satisfied with their hair, compared with 22% of the placebo group (ABI 17%, 95% CI 12 to 21, NNT six for 1 year).⁵

What other options are available? Topical minoxidil (eg, Rogaine®) is available over-the-counter at 2% strength and by prescription at 5% strength. Finasteride has not been compared with minoxidil. Other options include surgical hair implants and hairpieces.

What are the harms and risks of taking this drug?

In the randomized controlled trials, 4.2% of the finasteride group reported one or more adverse sexual experiences (decreased libido, erectile dysfunction, or ejaculation disorder) as compared with 2.2% of the placebo group (absolute risk increase 2.0%, number needed to harm 50 for 1 year [$P < .05$]).⁵ Long-term adverse effects are unknown at this time.

How long will I have to prescribe it? Continued treatment is needed to maintain benefit; if treatment is stopped, any benefit will be lost within 6 to 12 months.^{3,5}

How will I know that it is working? It is difficult to be certain in any individual case whether the drug is working. If a patient is not achieving the desired cosmetic effect in 6 to 12 months, there is no reason to continue.

What other facts should I know about this drug?

Finasteride is also prescribed at a higher dose under the trade name Proscar® for treatment of symptoms of



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Direct-to-consumer advertising in the United States in 1999 (US\$)

Advertising

- Pharmaceutical companies spent \$1.8 billion on DTCA, a 40% increase over 1998.
- \$1.1 billion was spent on television advertisements, a 70% increase over 1998.
- About 41% of DTCA spending was concentrated on 10 products, among them loratadine (Claritin®, \$137 million), finasteride (Propecia®, \$100 million), sildenafil (Viagra®, \$94 million), omeprazole (Prilosec®, \$80 million), and orlistat (Xenical®, \$76 million).

Sales

The 25 top-selling DTCA drugs accounted for 40.7%, or \$7.2 billion, of the overall \$17.7 billion (19%) increase in retail drug sales in 1999 over 1998. Doctors wrote 34.2% more prescriptions in 1999 than in 1998 for the top 25 DTCA drugs. Doctors wrote only 5.1% more prescriptions for all other prescription drugs.

benign prostatic hypertrophy because of its effect of decreasing prostate volume.⁸

The dose for male baldness (1 mg/d) and doses as low as 0.2 mg/d reduce dihydrotestosterone serum concentrations by approximately 70%, increase testosterone serum concentrations by about 20%, and variably decrease concentrations of prostate-specific antigen.^{3,5,6,9} The clinical importance and long-term consequences of these effects is unknown at this time.

Any contact with the drug is contraindicated for women who are pregnant or might become pregnant because the drug can cause abnormalities of the genitalia in male fetuses.

What are my legal liabilities if I give in to patient pressure and prescribe it? They are no different than for any other drug you prescribe.

What is it going to cost? Finasteride in 1-mg tablets for male pattern baldness costs on average \$1.60 daily. Finasteride in 5-mg tablets for symptoms of prostatic hypertrophy costs on average \$1.70 daily.

What happens if DTCA is deemed misleading?

Two advertisements for Propecia in *Time* magazine

were found to be misleading by the Division of Drug Marketing, Advertising and Communications, at the United States Food and Drug Administration (FDA). These advertisements stated, "One day science will create a pill for hair loss: That day is today." And "Starting today, you need not face the fear of more hair loss." In both cases, the FDA found the advertisements claimed a broader benefit than had been demonstrated and advised the company to discontinue the advertisements immediately. No other action was taken.

Conclusion

Direct-to-consumer advertising appears to increase drug sales and adds to pressure on busy clinicians. Before yielding to this pressure, physicians must be able to convey to patients in a meaningful way:

- the known benefits (eg, six men have to be treated for 1 year with finasteride for one man to be satisfied with the appearance of his hair);
- the known harms (eg, one in 50 men treated with finasteride for 1 year will have an adverse sexual experience); and
- the unknown risks (eg, long-term finasteride therapy is necessary to maintain benefit, and long-term effects are unknown at this time). ★

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