Baldness drug may cause sexual side effects: FDA

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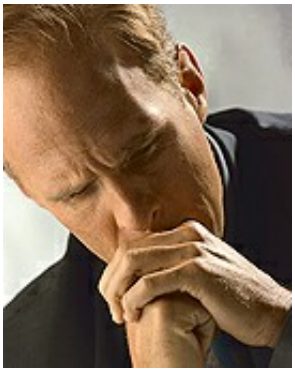

A related compound is prescribed to treat enlarged prostate glands.

(HealthDay) -- Two Merck & Co. drugs -- one to treat hair loss in men, the other to treat an enlarged prostate gland -- will get revised labels warning of potential sexual side effects that can last even after patients stop taking the drugs, the U.S. Food and Drug Administration said Thursday.

The two drugs -- Propecia to combat male pattern baldness, and Proscar, to treat enlarged prostates -- share the same chemical compound, called finasteride. One dose of Propecia contains 1 milligram of finasteride; one dose of Proscar contains 5 milligrams.

The new Propecia label will include a warning of "libido disorders, ejaculation disorders, and orgasm disorders that continued after

discontinuation of the drug," the FDA said in a news release.

The Proscar label will include a warning about "decreased libido that continued after discontinuation of the drug," the agency said.

The labels of both drugs will also carry about a description of reports of male infertility and/or poor semen quality that clears up or improves after the drugs are stopped.

Although a cause-and-effect relationship between the drugs and these side effects hasn't been established, case reports suggest there's a potential problem, the FDA said.

The agency added, however, that only a small percentage of men using these drugs have experienced an adverse sexual event.

The FDA said it believes the drugs are safe to take for their approved uses. It recommends that patients and their doctors consider the new information on the revised labels when weighing a best treatment option.

Last year, both drugs' labels were changed to warn of the possibility of erectile dysfunction even after discontinuing the drug, according to the FDA.

Dr. Anthony D'Amico, chief of genitourinary radiation oncology at Brigham and Women's Hospital in Boston, said Thursday that the revised labels contain "an important message that people need to hear."

"Particularly because Propecia is used by 20- and 30-year-olds for hair loss and these are people of childbearing age, so if they are getting issues with fertility that a big issue," he said.

In a statement released Thursday afternoon, Merck said:

"Merck believes that Propecia and Proscar are generally well tolerated and effective for their respective intended uses in accordance with their approved product labeling. In addition, please note that a causal relationship between the use of Propecia or Proscar and continued sexual dysfunction after discontinuation of treatment has not been established."

D'Amico said Thursday's announcement from the FDA "points up the usefulness of post-marketing studies on drugs that have been studied, but not for long enough periods to know what can happen when large numbers of people use them and what happens when they are discontinued."

More information: For more on the label changes, visit the U.S. Food and Drug Administration.