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US warns two drugs may have sexual side effects

By AFP | AFP - Sat, Apr 14, 2012

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Two Merck drugs for treating male baldness and enlarged prostate will now carry extended labels to add more possible sexual side effects, US regulators said.

The changes involve Propecia and Proscar, both of which contain the active ingredient finasteride, after patients reported additional adverse effects that were not apparent at the time of the drugs' approval, the US Food and Drug Administration said Friday.

The new Propecia label will include "libido disorders, ejaculation disorders, and orgasm disorders that continued after discontinuation of the drug," the FDA said. Propecia is a drug to treat male baldness.

Proscar, which treats symptoms of enlarged prostate, will now have a label that adds "decreased libido that continued after discontinuation of the drug."

In addition, both labels are being revised to "include a description of reports of male infertility and/or poor semen quality that normalized or improved after drug discontinuation," the FDA said.

FDA spokeswoman Stephanie Yao said the drugs were previously known to cause adverse sexual events in a small number of patients, and that information was included on labels at the time of approval.

The latest labeling change "expands the list of sexual adverse events reported to the FDA postmarketing," she told AFP, adding that "no new clinical studies were reviewed to evaluate these adverse events."

Proscar was approved for the US market in 1992 and Propecia in 1997. In 2011, both drugs' labels were "revised to include erectile dysfunction that continued after drug discontinuation," the FDA said.

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Last year, labels for Proscar and Propecia were also changed to advise of the possibility of an increased risk of high-grade prostate cancer.

The agency noted that even though "clear causal links between finasteride (Propecia and Proscar) and sexual adverse events have NOT been established, the cases suggest a broader range of adverse effects than previously reported in patients taking these drugs."

Since these side effects may be important to some patients, doctors were urged to discuss them with patients when deciding on treatment options.

In the case of Propecia, clinical trials showed 3.8 percent of men had reported one or more adverse sexual experiences, compared to 2.1 percent who were taking a placebo.

"Propecia and Proscar are generally well tolerated and effective for their respective intended uses in accordance with their approved product labeling," Merck said in a statement.

The company added that "a causal relationship between the use of Propecia or Proscar and continued sexual dysfunction after discontinuation of treatment has not been established," and expressed support for ongoing monitoring of adverse event reports.

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