Finasteride Label Changes 2012

On April 11, 2012, the U.S. Food and Drug Administration (FDA) announced changes to the professional labels for Propecia (finasteride 1 mg) and Proscar (finasteride 5 mg) to expand the list of sexual adverse events reported to FDA as some of these events have been reported to continue after the drug is no longer being used (note that erectile dysfunction after stopping use of these drugs was added as a known event in 2011). The new label changes include:

- A revision to the Propecia label to include libido disorders, ejaculation disorders, and orgasm disorders that continued after discontinuation of the drug.
- A revision to the Proscar label to include decreased libido that continued after discontinuation of the drug.
- A revision to both the Propecia and Proscar labels to include a description of reports of male infertility and/or poor semen quality that normalized or improved after drug discontinuation.

Despite the fact that 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. Information about these adverse events may be important to individual patients. Therefore, prescribers and patients need to be aware of them, as part of a discussion of risk and benefits of finasteride when determining the best treatment options.

Below are some additional questions and answers on this announcement and action.

Q: What are Proscar and Propecia?

A: Proscar and Propecia both contain the active ingredient finasteride and belong to a class of prescription medicines called 5 alpha-reductase inhibitors.

Proscar (finasteride 5 mg) was approved by FDA in 1992 and is indicated for the treatment of bothersome symptoms in men with benign prostatic hyperplasia (also referred to as BPH or an enlarged prostate). Proscar is also approved to reduce the risk of urinary retention or the need for surgery related to BPH.

Propecia (finasteride 1 mg) was approved by FDA in 1997 for use in males only and is indicated for the treatment of male pattern hair loss.

Q: Are any similar side effects already listed in the labels of Proscar and Propecia?

A: Yes. Sexual side effects were reported by patients during clinical trials, and this information was included in the Proscar and Propecia's labels at the time of approval in 1992 and 1997, respectively. In controlled clinical trials, these side effects resolved in patients who stopped finasteride, as well as in most patients who continued therapy. In 2011, both Proscar and

Propecia's labels were revised to include erectile dysfunction that continued after drug discontinuation.

Q: What studies and/or reports did FDA review to determine this information should be included in the label?

A: For Propecia, FDA reviewed 421 postmarketing reports of sexual dysfunction submitted to the Agency's Adverse Events Reporting System (AERS) database between 1998 and 2011. Of these, 59 cases reported sexual dysfunction that lasted for at least three months following discontinuation of Propecia, and included erectile dysfunction, decreased libido, problems with ejaculation and orgasm disorders.

For Proscar, FDA reviewed 131 cases of erectile dysfunction and 68 cases of decreased libido associated with the use of finasteride 5 mg submitted to the drug sponsor's worldwide safety database between 1992 and 2010. Where information was available, these reported events of erectile dysfunction and decreased libido lasted for at least several weeks after drug discontinuation.

Regarding semen quality, 251 cases associated with Propecia use were identified from the sponsor's safety database. Of these cases, 13 contained enough information for FDA to evaluate. FDA reviewed 29 cases associated with Proscar use, of which only 3 cases involved men with benign prostatic hypertrophy. There was limited information available on these cases to assess the effect of finasteride on semen quality.

FDA also requested additional information from the drug sponsor to assess the reports. No new clinical studies were reviewed to evaluate these adverse events. FDA is not aware of any additional controlled clinical studies conducted to evaluate these adverse events or to determine their cause or duration.

Q: Why are the label changes for Proscar and Propecia different?

A: The labels reflect the differences in the population of men using Propecia and Proscar, which have different indications of use. Postmarketing cases of sexual dysfunction that continued after patients stopped using Propecia occurred in a younger population of men compared to cases reported with Proscar. Older men who reported sexual adverse events with Proscar, in general, also had concurrent medical conditions and were treated with medications that may affect sexual function.

Q: Do all men experience sexual adverse events when using Propecia or Proscar?

A: No. Only a small percentage of men using these drugs have experienced a sexual adverse event. The frequency of sexual adverse events is best obtained from controlled clinical trials. Analysis of these controlled clinical trials showed that during treatment with Propecia, 36 (3.8%) of 945 men had reported one or more adverse sexual experiences as compared to 20 (2.1%) of 934 men who did not receive Propecia (received placebo).

Sexual adverse events associated with Proscar use were identified in two clinical trials. This information is included in the Proscar label. In one trial, these events were reported more frequently during the first year of treatment with Proscar as compared to men who received placebo. In years 2-4 of the trial, there was no significant difference between treatment groups in the incidences of impotence, decreased libido and ejaculation disorder.

Q: Has FDA notified healthcare professionals about the risk of sexual adverse events associated with finasteride use?

A: FDA has notified healthcare professionals who would normally prescribe finasteride products—dermatologists, family practice professionals, internists and urologists—about FDA's review of postmarketing reports and the label changes. This communication informs prescribers that FDA has not established a cause and effect relationship between finasteride and the sexual adverse events that continued after stopping drug use.

Q: I am currently taking Propecia or Proscar. What should I do?

A: If you have questions or concerns, you should consult your health care provider to discuss the risks and benefits of the medication as they specifically apply to you. Do not stop taking your medication without first consulting with your health care provider.

FDA believes that finasteride remains a safe and effective drug for its approved indications. Healthcare professionals and patients should consider this new label information when deciding the best treatment option.

Q: How do I report an adverse event to the FDA?

A: Patients and healthcare professionals should report adverse events experienced with Proscar or Propecia to the FDA MedWatch program. You can reach MedWatch at 1-800-332-1088, report online at MedWatch Online or submit your report using regular mail and postage-paid FDA Form 3500.

Source:

http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm299754.htm