AMERICAN HEALTH CARE

DRUG PRODUCTS & SAFETY NEWS

Diflucan Safety Announcement

April 26, 2016

The U.S. Food and Drug Administration (FDA) is evaluating the results of a Danish study that concludes there is a possible increased risk of miscarriage with the use of oral fluconazole (Diflucan) for yeast infections. They are also reviewing additional data and will communicate final conclusions and recommendations when the review is complete.

Health care professionals should be aware that the Centers for Disease Control and Prevention guidelines recommend only using topical antifungal products to treat pregnant women with vulvovaginal yeast infections, including for longer periods than usual if these infections persist or recur.

Patients who are pregnant or actively trying to get pregnant should talk to their health care professionals about alternative treatment options for yeast infections.

Oral fluconazole is used to treat yeast infections of the vaginal area, mouth, and esophagus, which is the tube that connects the mouth to the stomach. It is also used to treat a fungal infection of the brain and spinal cord that most often affects people with weakened immune systems, and used to prevent yeast infections that can spread to the rest of the body in cancer patients who have a weakened immune system. It is available under the brand name Diflucan and also as generics.

The current FDA drug label states that data available from studies in people do not suggest an increased risk of problems during pregnancy or abnormalities in developing babies when women are exposed to a single 150 mg dose of oral fluconazole to treat vaginal yeast infections. However, high doses of oral fluconazole (400-800 mg/day) taken by pregnant women for much longer than a single dose have resulted in reports of abnormalities at birth. In the Danish study, most of the oral fluconazole use appeared to be one or two doses of 150 mg.

Until FDA's review is complete and more is understood about this study and other available data, caution is advised when using oral fluconazole in pregnancy.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

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