

## FDA Drug Safety Communication

FDA to review study examining use of oral fluconazole (Diflucan) in pregnancy

**[04-26-2016]** The U.S. Food and Drug Administration (FDA) is evaluating the results of a Danish [study](#)<sup>1</sup> that conclude there is a possible increased risk of miscarriage with the use of oral fluconazole (Diflucan) for yeast infections. We are also reviewing additional data and will communicate our final conclusions and recommendations when our 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 called cryptococcal meningitis 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](#),<sup>1</sup> 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](#)<sup>1</sup> and other available data, we advise cautious prescribing of oral fluconazole in pregnancy.

We urge both healthcare professionals and patients to report adverse events involving fluconazole to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

### Reference

1. Molgaard-Nielsen D, Svanstrom H, Melbye M, et al. Association Between Use of Oral Fluconazole During Pregnancy and Risk of Spontaneous Abortion and Stillbirth. JAMA 2016; 315(1):58-67.