The FDA is warning the public that treatment with chronic, high doses (400-800mg/day) of Diflucan (fluconazole) during the first trimester of pregnancy may be associated with a rare and distinct set of birth defects in infants.

The FDA noted that the risk of birth defects does not appear to be associated with a single, low dose of Diflucan (fluconazole) used to treat vaginal candidiasis (yeast infections)

When is Diflucan prescribed?

- Fungal infections – including yeast infections of the vagina, mouth, throat, esophagus, abdomen, lungs, blood and other organs,
- Meningitis caused by fungus
- Treatment of infections as a result of chemotherapy or radiation therapy prior to a bone marrow transplant.

Currently, the FDA is warning that chronic use of Diflucan could cause:

- Brachycephaly (flat head syndrome)
- Abnormal facies
- Abnormal calvarial development
- Cleft palate
- Femoral bowing
- Think ribs and long bones
- Arthrogryposis (rare condition with stiff joints and abnormally developed muscles), and
- Congenital heart disease

Change in Pregnancy Class

As a result of the risk of birth defects, the FDA is changing the pregnancy category from category C to category D. Pregnancy category D means there is positive evidence of human fetal risk based on human data but the potential benefits from use of the drug in pregnant women with serious or life-threatening conditions may be acceptable despites its risks.

The pregnancy category for a single, low dose of fluconazole has not changed and remains category C.