

# Fluconazole (Diflucan®)

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This sheet is about exposure to fluconazole in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

## ***What is fluconazole?***

Fluconazole is a medication that has been used to treat yeast and fungal infections. It can be taken orally (by mouth), injected, or given by IV (into a vein). It is most commonly used as a single oral dose of 150 mg to treat vaginal yeast infections. For severe fungal infections involving the whole body, higher IV doses of up to 800 mg daily may be used. Fluconazole is sold under the brand name Diflucan®.

The Centers for Disease Control and Prevention (CDC) guidelines for treating vaginal yeast infections recommend using topical therapies instead of oral medication.

The product label for fluconazole recommends that people who are pregnant not use this medication except in cases of severe or potentially life-threatening fungal infections. For some people, the benefit of using fluconazole in pregnancy may outweigh the possible risks. Your healthcare providers can talk with you about what treatment is best for you.

## ***I take fluconazole. Can it make it harder for me to get pregnant?***

Studies have not been done to see if fluconazole can make it harder to get pregnant.

## ***Does taking fluconazole increase the chance of miscarriage?***

Miscarriage is common and can occur in any pregnancy for many different reasons. Information on whether taking fluconazole can increase the chance for miscarriage is mixed.

One study looking at almost 600 pregnancies suggested an increased chance for miscarriage if any dose of fluconazole was used during early pregnancy. A second study looking at miscarriages among people who filled a prescription for single-dose oral fluconazole for vaginal yeast infection between weeks 7 and 22 of pregnancy reported a slightly higher chance of miscarriage. Studies based on filled prescriptions or prescription records cannot tell if a person took the medication. Also, this study has other flaws that make it hard to confirm that the chance for pregnancy loss was truly higher in this group. It is also hard to confirm if the study outcomes are related to the medication or other factors.

Two studies involving over 500 pregnancies with low-dose oral fluconazole use in the months before or during their pregnancy did not find an increased chance for miscarriage. The U.S. Food and Drug Administration (FDA) made a statement in October 2019 saying available studies do not provide definite evidence of an increased chance for miscarriage with a single 150 mg dose of oral fluconazole.

## ***Does taking fluconazole increase the chance of birth defects?***

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Whether fluconazole increases the chance of birth defects likely depends on the dose and amount of time the medication is used.

A review of multiple studies including thousands of people who used low doses of fluconazole (150 to 300mg) found a small increased chance for heart defects but did not find an increased chance for most other birth defects, including cleft lip and/or palate (an opening in the upper lip and/or the roof of the mouth) or problems in the bones or skeleton.

A review of six studies reported that exposure to a dose higher than 150 mg in the first trimester slightly increases the chance of heart defects. A pattern of birth defects of the head, face, bones, and heart was reported in the five children of four people that took high doses (400 to 1200 mg per day) of fluconazole for many weeks in pregnancy to treat severe fungal infections. These cases on their own cannot prove that fluconazole caused these problems, but the unusual findings in these children have raised concern that the high dose of fluconazole may be the cause of the birth defects.

In summary, it is unlikely that the use of a single low dose of oral fluconazole during early pregnancy would greatly increase the chance of birth defects. The use of high-dose fluconazole for many weeks might be associated with an increased chance of birth defects.

***Does taking fluconazole in pregnancy increase the chance of other pregnancy-related problems?***

Studies have not found an increased chance of preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth) following a single dose of fluconazole. Studies including over 5500 pregnancies exposed to fluconazole did not find an increased chance for stillbirth.

***Does taking fluconazole in pregnancy affect future behavior or learning for the child?***

Studies have not been done to see if fluconazole can cause behavior or learning issues for the child.

***What screenings or tests are available to see if my pregnancy has birth defects or other issues?***

Prenatal ultrasounds can be used to screen for some birth defects, such as heart defects. Talk with your healthcare provider about any prenatal screenings or testing that are available to you. There are no tests available during pregnancy that can tell how much effect there could be on future behavior or learning.

***Breastfeeding while taking fluconazole:***

While it has not been well-studied during breastfeeding, fluconazole is commonly prescribed during this time. Fluconazole can enter breast milk and the amount in breastmilk is estimated to be less than the dose that would be given directly to the infant to treat an infection. The treatment of a vaginal infection often requires only a single dose of fluconazole and is unlikely to increase risks to the breastfed infant. If you suspect your baby has any symptoms (such as stomach upset or diarrhea), contact your child's healthcare provider.

If you have a yeast infection of the breast, your infant might also have oral thrush (a yeast infection in the mouth). If your child does have an infection, they will also need medical treatment, because the amount of fluconazole in breast milk is not enough to treat the nursing child. If you suspect your baby has oral thrush, contact your child's healthcare provider. Be sure to talk to your healthcare provider about all your breastfeeding questions.

***If a male takes fluconazole, could it affect fertility or increase the chance of birth defects?***

Studies have not been done in humans to see if fluconazole could affect male fertility (ability to get partner pregnant) or increase the chance of birth defects. One study in laboratory animals found lowered sperm count while the animal was exposed to fluconazole. Sperm counts returned to normal two months after stopping treatment. In general, exposures that fathers or sperm donors are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/>.

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