



RESEARCH AND RECENT STUDIES

Causes of Cleft Lip and Palate: FLUCONAZOLE

This information has been gathered by The Cleft Lip & Palate Foundation of Smiles. We are responding to the fact that a number of our members have questions concerning the safety of medications that they had taken during pregnancy, or may take during a future pregnancy. These medications may be the cause of craniofacial differences. Our goal is to ensure that our families have resources and facts about the medications that may be taken during pregnancy, so you can have informed discussions with the treating doctors.

Online at www.cleftsmile.org

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The Cleft Lip & Palate Foundation of Smiles provides research on craniofacial causes (genetics, environmental, prescription drugs), treatments (cleft palate teams, medical devices, therapies), and available support for families.

This PDF is about Fluconazole birth defect risks for women who get pregnant. The use of Fluconazole for childbearing-age women who are trying to treat a variety of yeast infections or for anti-fungal purposes raises difficult questions as to the importance of evaluating the risks vs. the benefits.



In August 2011, the [FDA issued a drug safety communication](#) warning the public that long-term use of the anti-fungal drug fluconazole high doses during the first trimester of pregnancy may be associated with birth defects in infants.

What Is Fluconazole?

Fluconazole is marketed as Diflucan and is used to treat a variety of yeast infections, pertaining to the mouth, throat, vagina, and other areas, and associated with oropharyngeal and esophageal candidiasis, vaginal candidiasis, and cryptococcal meningitis. It's also prescribed for its anti-fungal purposes to individuals undergoing radiation therapy and chemotherapy prior to a bone marrow transplant, and to those suffering meningitis due to a particular strain of yeast infection.

FDA Warning Of Associated Birth Defects

The FDA mandated additional product labeling and listed harmful doses of the medicine as 400 and 800 milligrams taken daily during an expecting woman's first trimester (the first three months of pregnancy). No advisory has been given by the FDA for using low, single doses (150 milligrams or less) to treat vaginal yeast infections.

At the higher dosage level, a number of published case reports indicate the occurrence of rare birth defects in infants of mothers who were treated with the drug during the first trimester of pregnancy. As a result of these studies, the FDA is changing the pregnancy category of fluconazole from category C to category D, which means that "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 despite its risks."



Craniofacial Differences including Cleft Palate tied to Fluconazole (Diflucan)

Birth defects associated with the product, according to the FDA, may include: “*abnormal facies, femoral bowing, abnormal development of the skullcap, brachycephaly, cleft lip or palate, thin ribs and long bones, congenital heart disease, and arthrogryposis.*”

Among the birth defects that research has linked to fluconazole are:

- Short, broad head
- Abnormal looking face
- Abnormal development of the skull cap
- Oral cleft defects
- Bowing of the thigh bones
- Thin ribs and long bones
- Muscle weakness and joint deformities
- Congenital heart disease

While most women will not be affected by this new warning, given that it only applies when Diflucan is prescribed at high dosages, if you have been prescribed Diflucan and are pregnant or contemplating pregnancy, it is still an important issue to discuss with your physician. Lower risk alternative treatment options may be available and women need to be fully informed about the risks prior to making these treatment decisions that affect the health of both mother and child.

Do you have more questions? Do you need resources?

For questions and resources about cleft lip and cleft palate, please contact: [The Cleft Lip and Palate Foundation of Smiles](#). Cleft lip or palate is one of the most common birth defects, currently affecting one in 600 children in the United States. The Foundation was formed by a young mother of twins both born with cleft lip and palate. The Foundation offers positive support to parents of children with craniofacial differences by offering

news, information on cleft palate teams, [state by state resources](#), [birth registry listings](#), and a [support group](#) where you can meet other families in your local area who are going through the same or similar concerns and where you can share and express useful information.

References

[FDA Drug Safety Communication: Use of long-term, high-dose Diflucan \(fluconazole\) during pregnancy may be associated with birth defects in infants.](#)

Other Research from The Cleft Lip & Palate Foundation of Smiles

Research and Recent Studies:

[Causes of Cleft Lip and Palate: Birth Defects](#)

[Causes of Cleft Lip and Palate: Clomid](#)

[Causes of Cleft Lip and Palate: Health Insurance](#)

[Causes of Cleft Lip and Palate: Hydrocodone](#)

[Causes of Cleft Lip and Palate: Special Education](#)

[Causes of Cleft Lip and Palate: SSRIs](#)

[Causes of Cleft Lip and Palate: Topamax](#)

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