

Birth Defects Research for Children

Special Report

Zofran and Birth Defects

Zofran is the trade name for ondansetron, a prescription drug that functions by blocking the body chemicals that cause nausea and vomiting. It is available in tablet form for oral consumption and by injection for direct delivery into the bloodstream.



Zofran was originally approved by the Food and Drug Administration (FDA) to treat chemotherapy (cancer) patients or post-surgery patients dealing with nausea.

It was never tested or approved for use during pregnancy. But when the drug manufacturer discovered the huge market for morning sickness medication, they began promoting the product for this particular purpose and this created an immediate problem. Zofran was not approved safe by the Food and Drug Administration (FDA) for women who are pregnant.

The FDA states that taking Zofran during pregnancy could potentially cause severe birth defects but regardless, it has not halted its use. Consequently, physicians continue to prescribe it regularly. Zofran has been associated with a variety of birth defects, including (but not limited to):

- Musculoskeletal abnormalities
- Club foot
- Cleft lip and/or palate
- Jaundice
- Heart deficiencies

Zofran has a black box warning that it may increase the risk of developing abnormal changes in the electrical activity of the heart which can result in a potentially fatal abnormal heart rhythm so the pregnant mother may be at risk as well.

The Justice Department fined the manufacturer of Zofran \$3 billion for falsely promoting their products. It was the largest settlement ever by a pharmaceutical company.

Fact Sheet by:
Birth Defect Research for
Children, Inc.
www.birthdefects.org