

## [Drug Injury Watch: Zofran Use During Pregnancy: Cleft Palate And Fetal Heart Malformations](#)

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on March 11, 2016)

In this December 2015 *Medscape Pharmacists* article, "[Zofran] Ondansetron in Pregnancy", there is mixed evidence in the medical literature about what birth defects specifically and the extent of that danger.

In that article, Darren J. Hein, PharmD, summarizes the findings of several medical studies concerning Zofran-associated birth defects, a few of which you will see below.

For his review of "National Birth Defects Prevention Study. Medications used to treat nausea and vomiting of pregnancy and risk of selected birth defects" (*Birth Defects Res A Clin Mol Teratol.* 2012;94:22-30), Dr. Hein writes:

A larger, case/control study associated [Zofran (ondansetron)] with a significantly increased risk for cleft palate. The odds of cleft palate were 2.4 times higher with exposure to [Zofran (ondansetron)] during the first trimester (n = 55) vs unexposed pregnancies (n = 4479); however, the risk for cleft lip, hypospadias, or neural tube defects was similar in both groups. [footnote omitted]

A second study for which Dr. Hein presents his summary of the findings is "Ondansetron use in early pregnancy and the risk of congenital malformations—a register based nationwide cohort study" (Program and abstracts of the 29th International Conference on Pharmacoepidemiology & Therapeutic Risk Management; August 25-28, 2013; Montreal, Quebec, Canada. Abstract 25. Abstract 25, Pregnancy session 1):

Another group of Danish researchers, using the same Medical Birth Registry and National Patient Register, evaluated the teratogenic effects of [Zofran (ondansetron)] exposure during the first trimester using 1997-2010 data. Of the 897,018 births in this timeframe, prescription records suggested that 1248 women were exposed to ondansetron. The odds of fetal heart malformation were two times higher in infants of women exposed to [Zofran (ondansetron)] compared with unexposed women; the risk for major birth defects overall was similar. [footnote omitted]

And lastly, we get his take on "Use of ondansetron during pregnancy and congenital malformations in the infant" (*Reprod Toxicol.* 2014;50:134-137):

Swedish researchers used the Swedish Medical Birth Register and Swedish Register of Prescribed Drugs to gather data on pregnancies and exposure to [Zofran (ondansetron)] early in pregnancy. During the period between 1998 and 2012, 1349 women received [Zofran (ondansetron)] in early pregnancy. [Zofran (ondansetron)] exposure was not associated with an increased risk for severe birth defects; however, the odds of general heart defects were 1.6 times higher, and the odds of heart septum defects were 2.1 times higher. [footnote omitted]

As seen by these studies done by several different groups of international medical researchers, the fetal risks associated with the use of Zofran or ondansetron during the first trimester of pregnancy remain unclear.

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- [With Zofran - Birth Defects Lawsuits Filed, How Will GlaxoSmithKline Update Its Drug Label To Comply With New FDA Rule Effective June 2015](#)
- [A 2004 Medical Journal Article Indicated A Possible Link Between The "Morning Sickness" Drug Use Of Zofran And Hypospadias](#)
- [Zofran Associated With Birth Defects When Used During Pregnancy As An "Off-Label" Morning Sickness Treatment](#)

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Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.  
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