

Zofran® Birth Defects Guide

Drug companies sometimes fail to adequately warn expectant mothers that certain drugs increase the chance of birth defects. According to the U.S. Food and Drug Administration (FDA), one of the most popular anti-nausea drugs on the market increases the risk that children will be born with birth defects. Zofran®, an anti-nausea drug developed by GlaxoSmithKline, is approved by the FDA to treat nausea in patients undergoing major surgery, chemotherapy or other strong cancer treatments. The FDA has not approved Zofran® to treat morning sickness.

Prescribing Zofran® to pregnant women is classified as an off-label use of the common prescription drug, yet many physicians continue to prescribe Zofran® to treat morning

sickness. Physicians who prescribed Zofran® off-label could have been influenced by GlaxoSmithKline. In 2012, GlaxoSmithKline struck a Zofran® settlement with the federal government to resolve allegations that it improperly marketed the anti-nausea drug as an off-label treatment for morning sickness.

Cory Watson attorneys are helping families determine whether a Zofran® prescription taken during pregnancy is responsible for birth defects including heart defects, atrial and septal defects (holes in the heart), cleft lip, cleft palate, kidney failure, club foot, malformation of the cranium and instances where the baby's organs have been malformed or malpositioned.

MORE ABOUT BIRTH DEFECTS LINKED TO ZOFRAN®:

1. Heart Defects and Heart Murmurs

Taking Zofran® while pregnant doubles your risk of having a child with Atrial or Ventricular Septal Defects, which are characterized by a hole in the wall of the chambers of the heart, present at birth.¹ The defect occurs in the early stages of pregnancy and must be treated immediately after birth by surgery or by ongoing medication during childhood.²

2. Cleft Lip and Cleft Palate

Taking Zofran® while pregnant doubles your risk of having a child with a cleft lip or palate deformity. The defect prevents the two sides of the face from joining together and usually occurs within the first 4 to 6 weeks of pregnancy.³ Babies born with cleft lip or cleft palate require surgery to treat the appearance, feeding, breathing and hearing issues associated with the birth defect. In most cases, multiple surgeries are required.

3. Kidney Failure

Zofran® is believed to increase the risk of kidney problems in infants whose mothers took Zofran® early in

pregnancy. The drug is linked to a six-fold increased risk of a malformation of the renal pelvis, causing urine buildup.⁴ This defect ultimately leads to permanent kidney damage or kidney failure which may require dialysis or a full kidney transplant.

4. Club Foot

Zofran® is tied to an increased risk of giving birth to a child with clubfoot, or talipes equinovarus. This defect causes the newborn to be born with one or both feet rotated in toward the ankle. The treatment of this potentially crippling condition is complex and often painful.⁵

5. Craniosynostosis (Skull Deformities)

Zofran® may cause cranial deformation; creating pressure on the brain which can lead to brain damage.

Cory Watson attorneys are helping families determine whether Zofran® caused their children's birth defects. For a confidential, free legal consultation call us (800) 900-4800 or fill out a confidential form on www.corywatson.com.

Never stop taking any medication without first consulting your doctor. Zofran® is a registered trademark of GlaxoSmithKline, Inc., and is used here only to identify the product in question. This law firm is not associated with, sponsored by, or affiliated with GlaxoSmithKline or the U.S. Food and Drug Administration

No representation is made that the quality of legal services to be performed is greater than the quality of legal services performed by other lawyers.

¹ Andersen, et al., *Ondansetron Use in Early Pregnancy and the Risk of Congenital Malformations – A Register Based Nationwide Control Study*, presented as International Society of Pharmaco-epidemiology, Montreal, Canada (2013).

² Danielsson, et al., *Ondansetron During Pregnancy and Congenital Malformations in the Infant*, *Reproductive Toxicology* (Oct. 31, 2014).

³ Mitchell, et al., *Medications used to treat nausea and vomiting of pregnancy and the risk of selected birth defects*. *Birth Defects Research* (2012).

⁴ Colvin, et al., *Off-Label Use of Ondansetron in Pregnancy in Western Australia*, *BioMed Research International* (Nov. 19, 2013).

⁵ Birth defects. *March of Dimes*. http://www.marchofdimes.com/baby/birthdefects_clubfoot.html#. Accessed Feb. 6, 2013.