



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Ondansetron (Zofran®)

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. This sheet talks about whether exposure to ondansetron may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

What is ondansetron?

Ondansetron is a medication used to treat nausea and vomiting that may be caused by surgery, chemotherapy or radiation therapy. Ondansetron has also been prescribed during pregnancy to reduce symptoms of nausea and vomiting in pregnancy (NVP). NVP is also referred to as “morning sickness”. For more information on NVP, please see the MotherToBaby fact sheet called Nausea and Vomiting in Pregnancy at <https://mothertobaby.org/fact-sheets/nausea-vomiting-pregnancy-nvp/pdf/>. Ondansetron is sold under the brand name Zofran®.

Can taking ondansetron during pregnancy cause birth defects?

Probably not. Most studies have found no increased chance for birth defects among thousands of women who used ondansetron in the first trimester. However, one study reported a small increased chance for cleft palate (an opening in the roof of the mouth that may be repaired with surgery) when ondansetron is used in the first trimester. Two other studies found a small increased chance for heart defects if ondansetron is used while the heart is forming during the first trimester (during 5 – 10 weeks of gestation). More studies are needed to know if ondansetron actually increases the chance for either cleft palate or heart defects. Due to these concerns, it may be best to wait until after 10 weeks gestation to take ondansetron, if possible, until more information is available.

Can taking ondansetron during pregnancy cause other pregnancy complications?

Studies did not find a higher chance of miscarriage, prematurity (being born before 37 weeks of pregnancy), or low birth weight when women used ondansetron during pregnancy.

At higher doses, there have been reports that ondansetron use might cause a heart rhythm problem (called QT interval prolongation) in the person taking ondansetron. In severe cases, this could become an abnormal heart rhythm known as Torsades de Pointes. You can discuss how to monitor for QT interval prolongation with your health care provider.

What can I do to help control my nausea and vomiting?

MotherToBaby has a helpful fact sheet on nausea of pregnancy with recommendations. You can review it here: <https://mothertobaby.org/fact-sheets/nausea-vomiting-pregnancy-nvp/pdf/>. Also, eating small meals often, drinking plenty of clear fluids, and avoiding triggers (such as odors, heat, and spicy or high fat foods) can help. Talk to your health care provider about which NVP treatments are right for you.

Is it safe to take ondansetron while I am breastfeeding?

There have been no studies in humans looking at the use of ondansetron during breastfeeding. Studies in animals suggest that ondansetron enters breast milk, but the effects of ondansetron on a breastfeeding infant are not known. Although ondansetron has been used in infants with no harmful effects reported, it is not approved for use in infants less than 1 month old. If ondansetron use is necessary, this is not a reason to stop breastfeeding but a different drug may be considered, especially while breastfeeding a newborn or preterm infant. Be sure to talk to your health care provider about all your choices for breastfeeding.

What if the father of the baby takes ondansetron?

There are no human studies looking at a father's use of ondansetron. Animal studies have not shown any effect on male fertility. In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

Selected References:

- Anderka M, et al. 2012. Medications used to treat nausea and vomiting of pregnancy and the risk of selected birth defects. *Birth Defects Res A Clin Mol Teratol* 94(1):22–30.
- Briggs GG, Freeman RK. 2014. *Drugs in pregnancy and lactation*. 10th edition. Philadelphia, PA: Wolters Kluwer (online version)
- Cohen R, et al. 2014. Intestinal obstruction in pregnancy by ondansetron. *Reprod Toxicol*. 2014 Oct 24;50C:152-153.
- Danielsson B, Wikner BN, Kallen B. 2014. Use of ondansetron during pregnancy and congenital malformations in the infant. *Reprod Toxicol* 50:134-7.
- Einarson AK, et al. 2004. The safety of ondansetron for nausea and vomiting of pregnancy: a prospective comparative study. *BJOG*;111:940-3.
- Elkomy MH, Sultan P, Carvalho B et al. Ondansetron pharmacokinetics in pregnant women and neonates: towards a new treatment for neonatal abstinence syndrome. *Clin Pharmacol Ther*. 2015;97:167-76.
- Fejzo MS, et al. 2016. Ondansetron in pregnancy and risk of adverse fetal outcomes in the United States. *Reprod Toxicol* 62: 87-91.
- Food and Drug Administration. 2012. FDA Drug Safety Communication: New information regarding QT prolongation with ondansetron (Zofran). <http://www.fda.gov/Drugs/DrugSafety/ucm310190.htm>. Accessed 7/2016.
- Larrimer MB. 2014. Antiemetic medications in pregnancy: a prospective investigation of obstetric and neurobehavioral outcomes. *Am J Obstet Gynecol* 210 (3): 270. e1-7
- Pasternak B. 2013. Ondansetron in pregnancy and risk of adverse fetal outcomes. *N Engl J Med* 368:814-823.

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