

# 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". Ondansetron is sold under the brand name Zofran <sup>®</sup>.

#### 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: <a href="https://mothertobaby.org/fact-sheets/nausea-vomiting-pregnancy-nvp/pdf/">https://mothertobaby.org/fact-sheets/nausea-vomiting-pregnancy-nvp/pdf/</a>. 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.

#### I take ondansetron. Can it make it harder for me to get pregnant?

Studies on women have not yet been done to see if ondansetron could make it harder for a woman to get pregnant. However, studies in animals did not find that ondansetron would affect the ability to get pregnant.

#### Does taking ondansetron increase the chance for miscarriage?

One study did not find a higher rate of miscarriage among women who reported using ondansetron in the first trimester of pregnancy.

## 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 an association with cleft palate. This study used interviews with the mothers to learn about the medications taken during pregnancy. This study found a small increased chance for cleft palate (an opening in the roof of the mouth that may be repaired with surgery). Two other studies reported an association with heart defects.

## Can taking ondansetron during pregnancy cause other pregnancy complications?

Studies did not find a higher chance of miscarriage, premature delivery (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 healthcare provider is you are using this medication.

### Can I 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. 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/.

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