

# **Ondansetron (Zofran®)**

This sheet is about exposure to ondansetron in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

#### What is ondansetron?

Ondansetron is a medication that has been used to treat nausea and vomiting following surgery, chemotherapy, or radiation therapy. Ondansetron has also been prescribed during pregnancy to help with symptoms of nausea and vomiting in pregnancy (NVP). NVP is also referred to as "morning sickness". A brand name for ondansetron is Zofran<sup>®</sup>.

Sometimes when women find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

MotherToBaby has a fact sheet on NVP in pregnancy at:

https://mothertobaby.org/fact-sheets/nausea-vomiting-pregnancy-nvp/.

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

It is not known if taking ondansetron can make it harder to get pregnant. Animal studies did not find that ondansetron affects the ability to get pregnant.

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

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not reported a higher chance of miscarriage with use of ondansetron in pregnancy.

# Does taking ondansetron increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at published data to try to understand if an exposure, like ondansetron, might increase the chance of birth defects in a pregnancy. A few studies reported a less than 1% (less than 1 in 100) increase in the chance for a cleft palate (an opening in the roof of the mouth that can be repaired with surgery) or a heart defect. Other studies have not confirmed these findings. Most studies have not reported an increased chance for birth defects among thousands of women who used ondansetron in pregnancy.

#### Does taking ondansetron in pregnancy increase the chance of other pregnancy-related problems?

Studies did not find a higher chance of pregnancy loss, preterm delivery (delivery before 37 weeks of pregnancy), or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth) when ondansetron was used during pregnancy.

When taken at high doses, there have been reports that ondansetron 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**. If you are taking ondansetron, talk to your healthcare provider about your dose and how to watch for changes in your heart rhythm.

### Does taking ondansetron in pregnancy affect future behavior or learning for the child?

One study looked at 78 infants who were exposed to ondansetron at any time during pregnancy. When examined between 7 days to 2 months of age, there were no unusual behaviors reported. A single follow-up survey asking about behavior was sent in by parent of about 25 of these children. The children were between  $1\frac{1}{2}$  years to  $5\frac{1}{2}$  years old. No behavior differences were reported in these children compared to children who were not exposed to ondansetron during pregnancy.

# **Breastfeeding while taking ondansetron:**

Information on the use of ondansetron during breastfeeding is limited. Side effects in breastfeeding infants have not



been reported. Ondansetron has been given directly to infants as young as 1 month of age. Be sure to talk to your healthcare provider about all your breastfeeding questions.

# If a man takes ondansetron, could it affect fertility or increase the chance of birth defects?

Studies have not been done to see if ondansetron could affect a man's fertility (ability to get a woman pregnant) or increase the chance of birth defects above the background risk. Animal studies have not shown any effect on a man's fertility. In general, exposures that fathers and sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Please click here for references.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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