Ondansetron (Zofran®)

This sheet is about exposure to ondansetron in pregnancy and while breastfeeding. This information is based on published research studies. 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 caused by surgery, chemotherapy, or radiation therapy. It is also sometimes prescribed during pregnancy to treat nausea and vomiting of pregnancy (NVP), also known as "morning sickness." MotherToBaby has a fact sheet on nausea and vomiting of pregnancy at: https://mothertobaby.org/fact-sheets/nausea-vomiting-pregnancy-nvp/. One brand name for ondansetron is Zofran®.

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

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. Studies in animals did not show any problems with getting pregnant when taking this medicine.

Does taking ondansetron increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Large studies, including tens of thousands of pregnancies, have not shown an increased 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 in 100 (1%) chance for a cleft lip and/or palate (an opening in the upper lip or the roof of the mouth) or a heart defect. Other studies have not confirmed these findings. Overall, studies including over 250,000 pregnancies exposed to ondansetron have not found an increased chance for birth defects.

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

Studies have not found a higher chance of stillbirth, preterm delivery (delivery before 37 weeks of pregnancy), or low birth weight (weighing less than 5 pounds, 8 ounces [2,500 grams] at birth) when ondansetron was used during pregnancy.

Very high doses of ondansetron can affect heart rhythm. In rare cases, this can cause a serious irregular heartbeat called *Torsades de Pointes*. This risk is for the woman taking ondansetron, not the fetus. If you are taking ondansetron, talk to your healthcare provider about your dose and whether you need any heart monitoring.

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

Studies of over 5,000 children exposed to ondansetron during pregnancy have not found an increased chance of behavioral or learning problems, including autism, attention deficit hyperactivity disorder (ADHD), or intellectual disability.

Breastfeeding while taking ondansetron:

Ondansetron passes into breast milk in small amounts. Side effects have not been reported in infants who were exposed to ondansetron through breast milk. Ondansetron has also been given directly to infants as young as 1 month of age when medically needed. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

Studies have not been done to see if ondansetron could affect male fertility (ability to make healthy sperm) or increase the chance of birth defects. Animal studies have not shown any effect on male fertility. In general, exposures in men are less likely 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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