Vedolizumab (Entyvio®)

This sheet is about exposure to vedolizumab 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 providers.

What is vedolizumab?

Vedolizumab is a type of medication called a monoclonal antibody. It has been used to help stop swelling and irritation of the gut caused by inflammatory bowel diseases such as ulcerative colitis (UC) and Crohn's disease (CD). Vedolizumab is given by intravenous infusion (IV) (directly to the bloodstream through a vein in the arm). The brand name for vedolizumab is Entyvio®. For more information about UC and CD, please see the MotherToBaby sheets on Inflammatory Bowel Disease (IBD) at https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/.

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 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 vedolizumab. Can it make it harder for me to get pregnant?

Limited information does not suggest that taking vedolizumab would make it harder to get pregnant.

Does taking vedolizumab increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not found a higher chance of miscarriage when vedolizumab is used during pregnancy.

Does taking vedolizumab 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 research studies to try to understand if an exposure, like vedolizumab, might increase the chance of birth defects in a pregnancy. Studies have not found a higher chance of birth defects when vedolizumab is used during pregnancy.

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

Studies have compared pregnancy outcomes of women taking vedolizumab during pregnancy to those of women taking some other medications to treat IBD and those of women without IBD. Overall, the studies have not found higher chances of preterm delivery (birth before week 37), poor growth of the fetus, or other pregnancy-related problems among women taking vedolizumab.

Having severe IBD or IBD disease flares during pregnancy can increase the chance of pregnancy-related problems.

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

It is not known if vedolizumab can increase the chance of behavior or learning issues for the child. Small studies looking at children who were exposed to vedolizumab during pregnancy reported typical growth and development up to 1 year of age.

Breastfeeding while taking vedolizumab:

Vedolizumab has not been well-studied for use during breastfeeding. It is expected to get into breast milk in small amounts. Very little of the medication is expected to be absorbed by infants who swallow these small amounts in breast milk. No increased risk of serious infection was reported in the first year of life among 64 infants exposed to vedolizumab through breast milk. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

defects?

Studies have not been done to see if vedolizumab could affect a man's fertility (ability to make healthy sperm). No birth defects were reported in 30 pregnancies in which the men used vedolizumab. In general, exposures that men 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/.

MotherToBaby is currently conducting a study looking at medications used to treat UC and CD in pregnancy. If you are interested in taking part in one of these studies, please call: 1-877-311-8972 or visit: https://mothertobaby.org/join-study/.

Please click here for references.

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

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