Vedolizumab (Entyvio®)

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

What is vedolizumab?

Vedolizumab is a medication that has been used to treat inflammatory bowel diseases such as ulcerative colitis (UC) and Crohn's disease (CD). It is a monoclonal antibody that helps stop gut inflammation (swelling and irritation). Vedolizumab is given by intravenous (IV) infusion (directly to the bloodstream through a vein in the arm). The brand name for vedolizumab is Entyvio®. For more information on UC and CD, please see the MotherToBaby fact sheet 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 suggests that taking vedolizumab does not 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. In studies with a total of about 600 births, no increased chance of miscarriage was reported when vedolizumab was 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. In studies with a total of about 600 births, no increased chance of birth defects was reported when vedolizumab was used during pregnancy.

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

It is not known if taking vedolizumab during pregnancy can increase the chance of other pregnancy-related problems, such as preterm delivery (birth before week 37), or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth.

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. Typical growth and development were reported in 1 study looking at 16 children who were exposed to vedolizumab during pregnancy.

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. Infants that are exposed to vedolizumab through breast milk are expected to absorb very little of the medication. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes vedolizumab, could it affect 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 get a woman pregnant). 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 vedolizumab and other 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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