Vedolizumab (Entyvio®)

This sheet talks about using vedolizumab in a pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

**What is vedolizumab?**

Vedolizumab is a prescription medication used to treat inflammatory bowel diseases such as ulcerative colitis (UC) and Crohn’s disease (CD). Vedolizumab is an antibody that helps to stop gut inflammation (swelling and irritation). Vedolizumab is given in a healthcare provider’s office by intravenous infusion (through a vein in the arm) every 8 weeks after an initial startup dosing period. Vedolizumab is sold under the brand name 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/pdf/.

**I take vedolizumab. Can it make it harder for me to become pregnant?**

Based on the data available, it is not known if vedolizumab can make it harder to become pregnant. An animal study done by the manufacturer did not find that fertility was lower with the use of vedolizumab.

**I just found out I am pregnant, should I stop taking vedolizumab?**

Talk with your healthcare providers before making any changes to how you take your medication(s). The benefits of taking vedolizumab and treating an inflammatory bowel condition during pregnancy need to be weighed against any possible concerns of continuing the treatment.

**Does taking vedolizumab increase the chance for miscarriage?**

Miscarriage can occur in any pregnancy. Information from limited studies suggest no increase in the chance of miscarriage when vedolizumab is used during pregnancy.

**Does taking vedolizumab increase the chance for birth defects?**

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. There are about 160 reports on the use of vedolizumab during pregnancy, most with normal pregnancy outcomes. Also, there is one controlled study with 73 people using vedolizumab for IBD. This study did not show an increase in the chance for birth defects in those taking vedolizumab when compared with others with IBD on different medications or with no treatment at all.

**Could taking vedolizumab cause other pregnancy complications?**

The data available do not report pregnancy complications.

**Does taking vedolizumab in pregnancy cause long-term problems in behavior or learning for the baby?**

Based on the data available, it is not known if vedolizumab can cause long-term problems in behavior or learning.

**Can I take breastfeeding while taking vedolizumab?**

Vedolizumab has not been studied for use during breastfeeding. There are some case reports of those who used this medication while nursing without problems in the nursing infant. Because vedolizumab is a very large protein, it is unlikely that very much of the medication is able to pass into breast milk. If it does enter breast milk, it is is poorly absorbed from the infant’s gut, so it is unlikely that the infant would be exposed to much of the medication. It is possible that babies born before 37 weeks of pregnancy (preterm delivery) with underdeveloped digestive systems may be able to absorb more of the medication in breast milk. Be sure to talk to your healthcare provider about your breastfeeding questions.

**I take vedolizumab. Can it make it harder for me to get my partner pregnant or increase the chance of birth defects?**

There are reports on 11 pregnancies in partners of men who use vedolizumab, with no birth defects reported. In
general, exposures that fathers or sperm donors have are unlikely to increase the risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/.

Please click here for references.