



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Vedolizumab (Entyvio®)

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. This sheet talks about whether exposure to vedolizumab may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

What is vedolizumab?

Vedolizumab is a prescription medication used to treat ulcerative colitis (UC) and Crohn's disease (CD). Vedolizumab is an antibody that helps to stop gut inflammation (swollen & irritated tissue). Vedolizumab is given in a health care provider's office by intravenous infusion (through a vein in the arm) every 8 weeks after an initial startup dosing period. Vedolizumab is marketed under the brand name Entyvio®.

How long does vedolizumab stay in the body? Should I stop taking it before I try to get pregnant?

People break down medication at different rates. On average, almost all of this medication is expected to be gone from the body 5 months after the last dose. You should discuss concerns about your vedolizumab infusions with your healthcare provider. 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.

For more information on UC and CD during pregnancy, please see the MotherToBaby fact sheet on Inflammatory Bowel Disease at <https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/>.

Can taking vedolizumab make it more difficult for me to become pregnant?

There are currently no studies on fertility and vedolizumab in humans. An animal study done by the manufacturer did not find that fertility was lower with the use of vedolizumab. At this time, it is not known if taking vedolizumab would make it more difficult for a woman to get pregnant.

Can taking vedolizumab increase the chance for a miscarriage?

Studies have not been done to see if vedolizumab could increase the chance for miscarriage.

Can taking vedolizumab during my pregnancy cause birth defects or other pregnancy complications?

There is limited information and no controlled studies on the use of vedolizumab during pregnancy. There are around 90 reports on vedolizumab use in human pregnancy, most with normal pregnancy outcome. Animal studies done by the manufacturer did not show an increased chance for birth defects when vedolizumab was used in pregnancy.

Can I take vedolizumab while breastfeeding?

Probably. Vedolizumab has not been studied for use during breastfeeding; however, there are some case reports of women who used this medication while nursing without problems in the nursing infant. Because vedolizumab is a very large protein, it is not likely that very much of the medication is able to pass into breast milk. Furthermore, vedolizumab is poorly absorbed from the gut, so it is unlikely that any of the medication that gets into breast milk would enter the baby's system from the GI tract. It is possible that premature babies (born before 37 weeks gestation) 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.

What if the father of the baby takes vedolizumab?

There are reports on 13 pregnancies in partners of men who use vedolizumab, with no birth defects reported. In general, exposure of the father is unlikely to increase the risk 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 sign up at <https://mothertobaby.org/join-study/>.

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May, 2018