



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 a protein that helps block the movement of white blood cells into the GI tract. These white blood cells help fight infection but also cause bowel inflammation in people with UC and CD.

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 medicines at different rates. On average it takes about 25 days for one half of the medicine to leave the body. Most of the medicine is expected to be gone from the body in 125 days (about 4 months).

You should discuss with your doctor any decision to stop vedolizumab infusions. The benefits of taking vedolizumab and treating an inflammatory bowel condition during pregnancy need to be weighed against the possible risks of continuing the medication. For more information on UC and CD during pregnancy, please see the MotherToBaby fact sheet on Inflammatory Bowel Disease at <http://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. Animal studies done by the manufacturer did not find that fertility was lowered with the use of vedolizumab in pregnancy. At this time, it is not known if taking vedolizumab would make it more difficult for a woman to get pregnant.

Can taking vedolizumab during my pregnancy cause birth defects?

Rabbit and monkey studies done by the manufacturer did not show an increased chance for birth defects when vedolizumab was used in pregnancy. These studies are reassuring; however, there have been no studies looking at the use of vedolizumab in human pregnancy.

Vedolizumab is a large protein. Because of this, it is thought that very little medicine can cross the placenta (the blood connection a pregnant woman shares with her baby) and reach the developing baby. Without information about the vedolizumab in human pregnancy, the risk to the developing baby is uncertain.

Can I take vedolizumab while breastfeeding?

Yes. Vedolizumab has not been studied for use during breastfeeding; however, because vedolizumab is a very large protein, it is not likely that very much of the medication would be able to pass into breast milk. Also, 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. 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 health care provider about all your breastfeeding questions.

What if the father of the baby takes vedolizumab?

There are no studies looking at possible risks to a pregnancy when the father takes vedolizumab. 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 and Pregnancy at <http://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/>.

MotherToBaby is currently conducting a study looking at vedolizumab and other medications used to treat autoimmune diseases in pregnancy. If you are interested in taking part in one of these studies, please call 1-877-311-8972 or sign up at <http://mothertobaby.org/join-study/>.

References:

- Entyvio® Prescribing Information. Available online at <http://general.takedapharm.com/content/file.aspx?filetypecode=ENTYVIOPI&CountryCode=US&LanguageCode=EN&cacheRam6d1f-4edf-8fc9-8cafced45ce5>.

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