



Certolizumab Pegol (Cimzia®)

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 certolizumab pegol 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 certolizumab pegol?

Certolizumab pegol is a prescription medication used to treat autoimmune conditions. It is called a tumor necrosis factor (TNF) inhibitor because it binds and blocks TNF, a substance in the body that causes inflammation in the joints, spine, and skin. Certolizumab pegol is given as an injection under the skin. It is sold under the brand name Cimzia®.

MotherToBaby has some fact sheets on some autoimmune conditions, such as:

- rheumatoid arthritis (<https://mothertobaby.wpengine.com/fact-sheets/rheumatoid-arthritis/pdf/>),
- psoriatic arthritis (<https://mothertobaby.wpengine.com/fact-sheets/psoriasis-and-pregnancy/pdf/>),
- ankylosing spondylitis (<https://mothertobaby.wpengine.com/fact-sheets/ankylosing-spondylitis/pdf/>),
- Crohn's Disease (<https://mothertobaby.wpengine.com/fact-sheets/inflammatory-bowel-disease-pregnancy/pdf/>).

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

Individuals break down medication at different rates. On average, it takes about 10 weeks after taking the last dose of certolizumab pegol, for most of the medication to be gone from the body. You should talk to your healthcare provider before you stop taking this medication. The benefits of taking certolizumab pegol and treating your autoimmune condition during pregnancy need to be weighed against the possible risks of stopping the medication. Women planning a pregnancy are recommended to take folic acid prior to pregnancy.

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

There are no human studies looking at whether taking certolizumab pegol would make it harder for a woman to get pregnant. Animal studies did not find an effect on fertility.

Does taking certolizumab pegol increase the chance for miscarriage?

Based on available research, it is unlikely that certolizumab would increase the chance for a miscarriage.

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

There is published data on over 500 pregnancies with exposure to certolizumab pegol. A higher rate of birth defects or stillbirth has not been reported.

It is unlikely that the developing baby will be exposed to very much of this medication. Studies that measured drug levels in the mothers' blood, cord blood and infant blood right after birth and up to eight weeks after delivery found little to no transfer of certolizumab pegol across the placenta to the developing baby. It is believed that the molecular structure of certolizumab pegol, which is different from other TNF inhibitors, is what keeps this medication from easily crossing the placenta. (The placenta is a temporary organ that develops during pregnancy and works as the blood connection between mom and the baby.)

Women with more severe autoimmune disease symptoms ("flares") may have a higher chance for pregnancy loss, preterm delivery, and babies that are small and have a low birth weight. However, certolizumab pegol medication use has not been associated with a greater chance for these complications.

Can I take certolizumab pegol in the third trimester of pregnancy?

Probably. Certolizumab pegol does not cross the placenta in significant amounts, in the third trimester. In a study of 16 women who used certolizumab pegol throughout pregnancy, certolizumab could only be detected in the blood of one infant at birth, and it was at a very low level. The results of other studies were similar. Given this data, it appears that certolizumab pegol may be used in the third trimester of pregnancy. Stopping the medication can lead to increased disease symptoms which might increase the chance for preterm delivery. Also, some people report that the medication does not work as well after stopping it for a period of time and then trying to restart. Discuss the use of certolizumab pegol in the later part of pregnancy with your healthcare providers.

Can my baby receive live vaccines before one year of age if I take certolizumab pegol later in pregnancy?

Maybe. In 2010 there was a report of a 3-month-old baby given a live BCG vaccine (to prevent tuberculosis) whose mom had used another TNF-inhibitor (infliximab) during pregnancy. This baby died of a suspected BCG infection that spread throughout the body. Although this has only been reported once, and it cannot be proven that the disease from the BCG and death were a result of the infliximab, experts have since recommended that newborns not be given vaccines with a live virus for the first six months, to allow any medication that was present at birth to be gone from their body. The concern is that if there is medication in the baby's body, it could mean that the baby might get a disease from the vaccine. Research on other TNF inhibitor medications showed that babies, exposed to those medications late in pregnancy had drug levels in their blood at birth. The medication was gone from their bodies by about six months of age. Finally, there was a concern that exposure during pregnancy could suppress the immune system in babies.

Recent research has found that infants exposed to certolizumab pegol in pregnancy are not at a higher risk of serious infections than infants not exposed to these medications. Babies exposed to biologics in pregnancy appear to have the same response to vaccines as babies not exposed to these medications and build antibodies as expected.

Certolizumab pegol is different from other TNF inhibitors, because it does not easily cross the placenta, and may not cross at all for some pregnancies. If you take certolizumab pegol late in pregnancy, your baby is unlikely to be born with drug levels in the blood; therefore an increased risk for infection with the use of live vaccines is not expected.

Most vaccines given in the first six months of life are noninfectious and can be given to a baby even if certolizumab pegol is present in his/her blood. Noninfectious vaccines are not live vaccines, meaning a person cannot get the infection from the vaccine. Live vaccines always carry a small chance that a person could contract the infection from the vaccine. Types of live vaccines given in the US include measles-mumps-rubella (MMR), varicella (chicken pox), and rotavirus vaccine. The rotavirus vaccine is the only live vaccine given to infants less than one year of age in the United States. The vaccine series must be started by 15 weeks of age. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children.

Always let your child's healthcare provider know of any medications or exposures you had during pregnancy and breastfeeding, including treatment with TNF inhibitors. Your child's healthcare provider can discuss the risks and benefits of live vaccines with you.

Can I take certolizumab pegol while breastfeeding?

Yes. Certolizumab pegol is a very large protein and not very much of the medication would pass into breast milk. A report that measured certolizumab pegol levels in breastmilk of 16 women found very low or undetectable levels. This study reported that growth and development were normal up to 1 year of age among the nursing children. Certolizumab pegol is not well absorbed from the gut, so any medication that gets into breast milk would be unlikely to enter the baby's system. It is possible that premature babies (born before 37 weeks) with digestive systems that are not fully developed may absorb more of the medication in breast milk. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

What if the father of the baby takes certolizumab pegol?

There are no studies looking at possible risks to a pregnancy when the father takes certolizumab pegol. In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at <https://mothertobaby.wpengine.com/fact-sheets/paternal-exposures-pregnancy/pdf/>.

MotherToBaby is currently conducting a study looking at certolizumab pegol and other medications used to treat autoimmune diseases in pregnancy. If you are interested in taking part in this study, please call 1-877-311-8972, or see: <https://mothertobaby.wpengine.com/ongoing-study/cimzia/>.

Please click [here](#) for references.

June, 2018