



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

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

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

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

Individuals break down medicines at different rates. On average, it takes about 10 weeks after taking the last dose of certolizumab pegol, for most of the medicine to be gone from the body. You should talk to your healthcare provider before you stop taking any medication. The benefits of taking certolizumab pegol and treating your autoimmune condition during pregnancy need to be weighed against the possible risks of continuing the medication.

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

There are no human studies looking at whether certolizumab pegol causes fertility problems. Some animal studies did not find any effect on fertility.

Can taking certolizumab pegol during my pregnancy cause birth defects?

Currently, there are no published studies on certolizumab in pregnancy. Most of the information on certolizumab pegol use in pregnancy is from a small number of individual cases, which have not reported birth defects. One study looking at pregnancies exposed to any of the TNF inhibitors reported a slightly greater chance of birth defects, but none of the reported cases in this study involved certolizumab pegol. The study also found a slightly greater chance of a preterm birth (born before 37 weeks gestation) when using TNF inhibitors. However, this study compared women taking TNF inhibitors to healthy pregnant women, rather than other women with autoimmune diseases. At this time, it does not appear that certolizumab pegol increases risk of birth defects.

Certolizumab pegol does not easily cross the placenta. The placenta is a temporary organ that develops during pregnancy and works as the blood connection between you and your baby. Therefore, it is unlikely that the baby will be exposed to very much of this medication.

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

Certolizumab pegol does not readily cross the placenta in the third trimester. A number of small studies have looked at the levels of certolizumab in the infant blood in women who used the drug throughout pregnancy. 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 at a low level. The results of other studies were similar. Given this data, it appears that certolizumab pegol could be used in the third trimester of pregnancy. The decision to use certolizumab pegol in the later part of

pregnancy should be discussed with your healthcare provider, and may be based on your condition and the severity of your symptoms.

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

Most vaccines given in the first 6 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 a person could contract the infection from the vaccine. However, live vaccines usually contain a milder (attenuated) form of the virus or bacteria than what you might be exposed to otherwise. Types of live vaccines 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. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children. The rotavirus vaccine is a routine recommended immunization for infants in the US, and is the best way to protect infants against rotavirus disease.

There is a single report of a mother treated with another TNF inhibitor (infliximab) during pregnancy whose infant received a live BCG vaccine (to prevent tuberculosis) at 3 months of age. The baby later died of a suspected BCG infection that spread throughout the body. However, it is not known if exposure to infliximab was at all related. The BCG vaccine is not usually given in the US; it is used in other countries where tuberculosis infections are common.

Always be sure to let your pediatrician know of any medications or exposures you had during pregnancy and breastfeeding, including treatment with TNF inhibitors. Your pediatrician can discuss the risks and benefits of live vaccines with you.

Can I take certolizumab pegol while breastfeeding?

Because certolizumab pegol is a very large protein, not very much of the medication would be able to pass into breast milk. Reports on a small number of women who breastfed their infant while using certolizumab pegol suggested that certolizumab pegol levels in breast milk are very low. A study of 17 women in 2017, showed little to no levels of certolizumab pegol in the breast milk. Also, certolizumab pegol is not well absorbed from the gut, so any of the 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 be able to absorb more of the medication in breast milk. Be sure to talk to your health care provider about all your choices for breastfeeding.

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.org/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 sign up at <https://mothertobaby.org/join-study>.

References Available By Request

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