Certolizumab Pegol (Cimzia®)

This sheet is about exposure to certolizumab pegol in pregnancy and while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

What is certolizumab pegol?

Certolizumab pegol is a medication that has been used to treat some 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 sold under the brand name Cimzia®.

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

- Rheumatoid arthritis (https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/),
- Psoriasis and Psoriatic Arthritis (https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/),
- Ankylosing spondylitis (https://mothertobaby.org/fact-sheets/ankylosing-spondylitis/),
- Inflammatory Bowel Disease (https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/).

Sometimes when women find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. However, it is important to talk with your healthcare providers before making any changes to how you take this medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

I take certolizumab pegol. Can it make it harder for me to get pregnant?

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

Does taking certolizumab pegol increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not found a higher rate of miscarriage with the use of certolizumab pegol in pregnancy.

Does taking certolizumab pegol increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. There is published data on over 2,000 pregnancies with exposure to certolizumab pegol. A higher chance of birth defects has not been reported.

Does taking certolizumab pegol in pregnancy increase the chance of other pregnancy-related problems?

Severe autoimmune disease symptoms (“flares”) have been associated with a higher chance for pregnancy complications, such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth). In a small review of 14 pregnancies with exposure to certolizumab pegol, all infants were born full term, only 1 infant had low birth weight, and no infant infections were reported in the first 6 months after delivery.

It is unlikely that the developing baby will be exposed to very much of this medication in pregnancy. Studies that measured drug levels in blood of pregnant women, and in the umbilical cord blood and infant blood found little to no transfer of certolizumab pegol across the placenta to the developing baby. (The placenta is a temporary organ that develops during pregnancy and works as the blood connection between the pregnant woman and the baby). Certolizumab pegol was not found in the cord blood of 13 out of 14 babies. It was only found in very small amounts in the cord blood of 1 baby.

Does taking certolizumab pegol in pregnancy affect future behavior or learning for the child?

Studies have not been done to see if certolizumab pegol can increase the chance of behavior or learning issues for the child. A study that included certolizumab pegol along with other biologic medications found no differences in developmental milestones in the infants' first year of life.

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

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. Most vaccines given to infants less than one year of age are noninfectious. Noninfectious (non-live) vaccines can be given to a baby even if certolizumab pegol is taken during pregnancy. Live vaccines usually contain a weakened form of the virus or bacteria that it vaccinates against. Live vaccines pose a very small chance a person could get the infection from the vaccine. Live vaccines are usually not given to people using TNF inhibitors. Research has reported that infants exposed to certolizumab pegol in pregnancy were not found to be at a higher risk of serious infections than infants not exposed to these medications. Vaccines protect babies from getting common infections that can sometimes cause serious or even life-threatening illness. In the United States, the rotavirus vaccine is the only live vaccine given to infants less than one year of age. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children. Your pediatrician or healthcare provider can further discuss the risks and benefits of live vaccines with you.

Breastfeeding while taking certolizumab pegol:

Certolizumab pegol is a very large protein and not very much of the medication is expected to pass into breast milk. A report that measured certolizumab pegol levels in the breastmilk of 17 women found very low or undetectable levels. Certolizumab pegol is also not well absorbed when swallowed, so any medication that gets into breast milk would be less likely to enter the baby's blood system. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes certolizumab pegol, could it affect his fertility or increase the chance of birth defects?

Studies have not been done to see if certolizumab pegol could affect a man's fertility (ability to get a woman pregnant) or increase the chance of birth defects. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/

Please click here for references.

MotherToBaby is currently conducting a study looking at certolizumab pegol and other medications used to treat autoimmune disease 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/.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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