Certolizumab Pegol (Cimzia®)

This sheet talks about exposure to certolizumab pegol in a pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare 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 fact sheets on some autoimmune conditions, such as:

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

There are currently 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.

**I just found out that I am pregnant. Should I stop taking certolizumab pegol?**

Talk with your healthcare providers before making any changes to your medication(s). Your healthcare provider can help you decide if you should continue taking certolizumab pegol or if other medications may be more appropriate to treat your condition.

**Does taking certolizumab pegol increase the chance for miscarriage?**

Miscarriage can occur in any pregnancy. A study involving 79 pregnancies showed no increased chance in pregnancy loss when taken in the recommended doses.

**Does taking certolizumab pegol increase the chance of birth defects?**

In every pregnancy, a woman starts with a 3-5% chance of having a baby with a birth defect. This is called her background risk.

There is published data on over 500 pregnancies with exposure to certolizumab pegol. A higher rate of birth defects 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 pregnant woman’s 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. (The placenta is a temporary organ that develops during pregnancy and works as the blood connection between the pregnant woman and the baby).

**Could taking certolizumab pegol cause other pregnancy complications?**

Certolizumab pegol does not cross the placenta in large amounts in the second and third trimester. In a different 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.

Women with more severe autoimmune disease symptoms (“flares”) may have a higher chance for pregnancy complications.
loss, delivery before 37 weeks of pregnancy (preterm delivery), and babies that are small and have a low birth weight. However, the use of certolizumab pegol has not be associated with a greater chance for these complications.

Does taking certolizumab pegol in pregnancy cause long-term problems in behavior or learning for the baby?

Studies have not been done on the possible long-term effects of certolizumab pegol on the developing baby.

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

In 2010 there was a report of a 3-month-old baby given a live BCG vaccine (to prevent tuberculosis) whose mother had used another TNF-inhibitor (infliximab) during pregnancy. This baby died of a suspected BCG infection that spread throughout the body. This has only been reported once, and it cannot be proven that the disease 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 a live 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.

There was also a concern that exposure during pregnancy could lower the immune system in babies. Recent 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. 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, so 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 their 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 breastfeed 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 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 babies born before 37 weeks of pregnancy with digestive systems that are not fully developed may absorb more of the medication in breast milk. Be sure to talk to your health care provider about all of your breastfeeding questions.

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

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 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 see: https://mothertobaby.org/ongoing-study/cimzia/.

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