Tocilizumab (Actemra®)

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 tocilizumab 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 tocilizumab?

Tocilizumab is a prescription medication used for the treatment of rheumatoid arthritis (RA) and giant cell arteritis. Tocilizumab is an antibody (a protein made by the body’s immune system) that binds and blocks IL-6 (a protein that causes inflammation). Tocilizumab is used to reduce symptoms and joint damage in patients with rheumatoid arthritis and juvenile idiopathic arthritis (JIA). Tocilizumab is given in a healthcare provider’s office once a month as an infusion into a vein. It can also be injected under the skin. Tocilizumab is sold under the brand name Actemra®.

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

Individuals break down medications at different rates. On average, it can takes about 11 to 13 days for half of the medicine to leave the body of a non-pregnant adult. This means that about 2 and 1/2 months after taking the last dose of tocilizumab, most of the medication will be gone from the body.

You should not stop taking this medication without first talking with your healthcare provider. If a woman’s autoimmune condition worsens during pregnancy, it can increase risks to the pregnancy. It is important to weigh the benefits of treating RA or JIA during pregnancy against the possible risks of taking this medication. For more information about RA and pregnancy, please see our fact sheet at: https://mothertobaby.wpengine.com/fact-sheets/rheumatoid-arthritis/pdf/.

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

There are no studies looking at whether tocilizumab affects fertility in women. At this time, it is not known if taking tocilizumab would make it more difficult for a woman to get pregnant.

Can taking tocilizumab during my pregnancy increase the chance of miscarriage?

We’re not sure. Some recent studies have shown that taking a medication like tocilizumab increase the chance of miscarriage. However, in these studies, the women were older, which is a known risk for miscarriage, and some were also taking a medication called methotrexate, which can increase the risk for miscarriage on its own. Furthermore, in some of these studies, once women realized that they were pregnant, they stopped taking tocilizumab, which had been controlling their RA. Having increased RA symptoms can increase the chance for miscarriage. We need more research to determine if tocilizumab, itself, or other factors, have an effect on the chance for miscarriage.

Can taking tocilizumab during my pregnancy cause birth defects?

It does not appear that exposure to tocilizumab would significantly increase the chance of having a baby with a birth defect. No increased chance for having a baby with a birth defect has been seen in clinical trials and several published studies involving over 200 pregnancies where the mother took tocilizumab.

Tocilizumab is a large protein. Because of this, it is thought that a very small amount of the medication can cross the placenta (the blood connection a pregnant woman shares with her baby) and reach the developing baby during the first trimester.
Can taking tocilizumab cause other pregnancy complications?

This is unclear. Some studies have shown an increased rate of preterm delivery and low birth weight when a woman takes tocilizumab throughout pregnancy. We need more research to determine if this finding is due to tocilizumab or to the mom’s medical condition. Women with poorly controlled RA have a higher chance for preterm delivery (baby born before 37 weeks) and for babies to have low birth weight or be too small. RA flares (increase in symptoms) and inflammation can also increase the chance for pregnancy complications like preterm delivery and preeclampsia (a dangerous rise in blood pressure and increase of protein in the urine).

Will taking tocilizumab have any long-term effects on my baby’s behavior and development?

We don’t know. Because the medication is relatively new, approved by the FDA in 2010, we will need to conduct more research to determine if there are long-term effects. Based on the structure of tocilizumab, more of the medication may cross the placenta in the second and third trimesters. More research is needed to determine if this negatively affects the fetus, or has effects on the child later in life.

Can I take tocilizumab while breastfeeding?

There has been little research looking at the use of tocilizumab use during breastfeeding. In one study, two women resumed taking tocilizumab while nursing and no health problems were reported for their babies. Because tocilizumab is a very large protein, in theory it would be unlikely that very much of the medication would be able to pass into breast milk. In addition, absorption by the baby is unlikely because it would be destroyed by the infant’s gastrointestinal tract. If your baby is born preterm (prior to 37 weeks), absorption may be somewhat greater until the baby matures. In this case, it is important to consider the benefits of breast milk and treating the mother’s condition, as well as the potential unknowns of taking tocilizumab while nursing. Be sure to talk to your health care provider about all your breastfeeding questions.

What if the father of the baby takes tocilizumab?

There are no studies looking at possible risks to a pregnancy when the father takes tocilizumab. 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 tocilizumab 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.wpengine.com/join-study/.

Please click here to view references.