Tocilizumab (Actemra®)

This sheet talks about exposure to tocilizumab in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is tocilizumab?
Tocilizumab is a prescription medication used for the treatment of rheumatoid arthritis (RA) and giant cell arteritis in adults. 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®.

I take tocilizumab. Can it make it harder for me to get pregnant?
Studies have not been done to see if tocilizumab could make it harder for a woman to get pregnant.

I just found out I am pregnant. Should I stop taking tocilizumab?
Talk with your healthcare providers before making any changes to this medication. 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, please see our fact sheet at https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/pdf/.

Does taking tocilizumab increase the chance for miscarriage?
Miscarriage can occur in any pregnancy. Some recent studies have shown that taking a medication like tocilizumab may 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 chance for miscarriage on its own. Also, 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. More research is needed to determine if the use of tocilizumab or other factors have an effect on the chance for miscarriage.

Does taking tocilizumab in the first trimester increase the chance of birth defects?
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. It does not appear that exposure to tocilizumab would significantly increase the chance of having a baby with a birth defect above the background risk. 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 pregnant woman 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.

Could taking tocilizumab in the second or third trimester cause other pregnancy complications?
Based on the structure of tocilizumab, more of the medication may cross the placenta in the second and third trimesters. Some studies have shown an increased rate of preterm delivery (baby born before 37 weeks of pregnancy) and low birth weight when a woman takes tocilizumab throughout pregnancy. It is not known if this finding is due to
tocilizumab or to the mother’s medical condition. Women with poorly controlled RA have a higher chance for preterm delivery 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).

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

Studies have not been done to see if tocilizumab can cause long-term problems in behavior or learning.

**Can I breastfeed while taking tocilizumab?**

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. In another study, a women used tocilizumab during pregnancy and continued use after her baby was born. The baby did not have any health problems and did not show delayed milestones at six months of age.

Because tocilizumab is a large protein, it is thought that not very much of the medication enters breastmilk. Also, absorption by the baby is unlikely because it would be destroyed by the infant’s gastrointestinal tract. Preterm infants may absorb more of the medication until they mature. Be sure to talk to your healthcare provider about all your breastfeeding questions.

**If a man takes tocilizumab, could it affect his fertility (ability to get partner pregnant) or increase the chance of birth defects?**

In a report of 13 cases in which men who fathered children were taking tocilizumab, the babies did not have a higher risk of birth defects. 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/](https://mothertobaby.org/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.org/join-study/](https://mothertobaby.org/join-study/).**

Please click here to view references.

January, 2020