

Tocilizumab (Actemra®)

This sheet is 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 has been sold under the brand name Actemra®. Tocilizumab contains an antibody (a protein made by the body's immune system) that binds and blocks IL-6. IL-6 is a protein that causes inflammation in the body. Tocilizumab is used to reduce symptoms and joint damage in patients with rheumatoid arthritis and juvenile idiopathic arthritis (JIA). The product label for Actemra® states that until additional information is available, tocilizumab is not currently recommended for treatment of rheumatic and musculoskeletal disease during pregnancy and tocilizumab should be discontinued once pregnancy is confirmed.

Tocilizumab has recently been given FDA emergency use authorization for treatment of serious cases of COVID-19 pneumonia. Because there is limited outcome data specific to pregnancy, the National Institutes of Health (NIH) indicate that tocilizumab is not currently recommended for treatment of COVID-19 in pregnancy. However, they also state that potentially effective treatments should not be withheld from pregnant people because of theoretical concerns related to the safety of using those agents in pregnancy.

Sometimes when people 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 tocilizumab. Can it make it harder for me to get pregnant?

It is not known if tocilizumab can make it harder to get pregnant.

Does taking tocilizumab increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. Some studies have shown that taking a medication like tocilizumab may increase the chance of miscarriage. However, in these studies, the people were older, which is a known risk for miscarriage. In addition, some were also taking a medication called methotrexate which can increase the chance for miscarriage on its own. Also, in some of these studies, when they 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 learn if the use of tocilizumab or other factors have an effect on the chance for miscarriage.

Does taking tocilizumab 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. 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 or pattern of birth defects 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 only a very small amount of the medication can cross the placenta and reach the developing baby during the first trimester.

Does taking tocilizumab in pregnancy increase the chance of other pregnancy related problems?

Based on the structure of tocilizumab, more of the medication might cross the placenta in the second and third trimesters of a pregnancy. Some studies have shown an increased rate of preterm delivery (baby born before 37 weeks of pregnancy) and low birth weight (weighing less than 5 pounds, 8 ounces (2500 grams) at birth) when tocilizumab is used throughout pregnancy. It is not known if this finding is due to tocilizumab or to the medical condition being treated. People 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).

Published information on over 600 pregnant people who were given tocilizumab as treatment for COVID-19 pneumonia reported an increased chance for pregnancy loss and premature delivery. It is not possible to tell whether this was due to the tocilizumab or the severe illness and other medications which were also used to treat the condition.

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

Studies have not been done to see if tocilizumab can cause behavior or learning issues for the child. It is not known whether tocilizumab use in pregnancy influences the baby's developing immune system.

Breastfeeding while taking tocilizumab:

Tocilizumab gets into breastmilk in small amounts, and no adverse effects have been reported in exposed infants. This information is based on published reports of around 10 people who used tocilizumab while breastfeeding.

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. Infants that are born preterm or are younger than one month of age have a stomach and intestines that are less mature than older babies. This may allow more medication to enter their blood stream. If you suspect the baby has any symptoms, contact the child's healthcare provider. And be sure to talk to your healthcare provider about all your breastfeeding questions.

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

In a report of 13 cases, there was not a higher risk of birth defects noted. 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/>.

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/>.

Please click [here](#) to view references.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at [MotherToBaby.org](https://mothertobaby.org).

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