# **Tocilizumab (Actemra®)**

This sheet is about exposure to tocilizumab 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 tocilizumab?

Tocilizumab is a prescription medication that has been used to treat rheumatoid arthritis (RA), giant cell arteritis in adults, and juvenile idiopathic arthritis (JIA) in children. It has also been used to treat symptoms of severe COVID-19 in hospitalized patients. A brand name of tocilizumab is Actemra<sup>®</sup>.

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 your 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 of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Some studies have suggested that taking tocilizumab might increase the chance of miscarriage. However, the pregnancies in these studies also had other factors that are known to increase the chance of miscarriage, including older age during pregnancy and the use of certain other medications. Also, some people in the studies who were taking tocilizumab to control their RA stopped taking the medication when they realized they were pregnant, which could lead to an increase in RA symptoms. Having untreated RA symptoms can also increase the chance of miscarriage. As there can be many causes of miscarriage, it is hard to know if a medication, the medical condition, or other factors are the cause of a 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. Tocilizumab has not been found to increase the chance of birth defects above the background risk. It is reassuring that tocilizumab is not expected to cross the placenta and reach the pregnancy in large amounts during the first trimester, which is the time when a birth defect is most likely to happen.

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

Tocilizumab might cross the placenta in higher amounts in the second and third trimesters of pregnancy. Some studies have shown an increased chance of pregnancy complications including preterm delivery (birth before week 37) and low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth) when tocilizumab is used throughout pregnancy to treat conditions such as RA. However, since poorly controlled RA can also increase the chance for preterm delivery, low birth weight, babies born smaller than expected, and other pregnancy complications, it is not known if these findings are due to tocilizumab or to the medical condition being treated.

Published reports of people who have received tocilizumab to treat severe COVID-19 during the second or third trimesters of pregnancy have not identified an increased chance of pregnancy problems or problems for newborns related to the medication. The pregnancy-related problems reported in these cases, such as preterm delivery, c-section, or admission to the neonatal intensive care nursery (NICU) were believed to be because of the severe COVID-19 infection or other underlying medical conditions or complications.

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

A report of 3 infants exposed to tocilizumab throughout the pregnancy reported no problems with their development up to 1 year of age. In a study that looked at infants who were exposed to tocilizumab for a short time during the second or third trimesters of the pregnancy, 4 infants were followed up to 6 months of age and 14 infants were followed up to age 1 year, with no problems reported in their development.

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#### Can my child receive live vaccines if I take tocilizumab during pregnancy?

Since tocilizumab may suppress the immune system of the person taking it, there is a theoretical concern that the same thing could happen to the baby if they are exposed during pregnancy. If someone has a weakened immune system they may be more likely to develop an infection from a live vaccine. Live vaccines contain a small amount of live virus. Inactivated vaccines do not contain live virus, so they cannot cause the disease they protect against. In the United States, rotavirus is the only live vaccine routinely given in the first year of life. Most people can get inactivated vaccines in the first year of life.

Talk with your child's healthcare provider about your exposure to tocilizumab during pregnancy. They can talk with you about the vaccines your child should receive and the best time for your child to receive them.

#### Breastfeeding while taking tocilizumab:

Based on case reports and the fact that tocilizumab is a large protein, it is thought that not very much of the medication gets into breast milk. Also, any small amounts of tocilizumab in the milk are likely to be destroyed in the baby's stomach instead of being absorbed into their system. Infants that are born preterm or are younger than one month of age might be able to absorb higher amounts of medication in the milk. No adverse effects have been reported in infants exposed to tocilizumab through breast milk. If you suspect the baby has any symptoms, such as fever or diarrhea, contact the child's healthcare provider. Be sure to talk to your healthcare provider about all your breastfeeding questions.

#### If a male takes tocilizumab, could it affect fertility or increase the chance of birth defects?

Studies have not been done to see if tocilizumab could affect male fertility (ability to get partner pregnant). There was no increase in birth defects in a report that included 8 infants born to males who used tocilizumab. 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.

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

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