

Tofacitinib (Xeljanz®, Xeljanz XR®)

This sheet is about exposure to tofacitinib 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 tofacitinib?

Tofacitinib is a medication that has been used to treat rheumatoid arthritis, psoriatic arthritis, and ulcerative colitis. You can find more information on these conditions in the MotherToBaby fact sheets at

https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/,

https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/ and

https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/. A brand name of tofacitinib is Xeljanz® and Xeljanz XR®.

Tofacitinib is also being studied to treat severe COVID-19. Since there is little information about tofacitinib in pregnancy and breastfeeding, it is not currently recommended for treatment of COVID-19 in people who are pregnant or breastfeeding if other recommended treatment options are available. However, the National Institutes of Health (NIH) also state that necessary COVID-19 treatments should not be withheld from people just because they are pregnant or breastfeeding. More information on COVID-19 can be found in our fact sheet here: https://mothertobaby.org/fact-sheets/covid-19/.

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 tofacitinib. Can it make it harder for me to get pregnant?

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

Does taking tofacitinib increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not been done to see if tofacitinib increases the chance of miscarriage. Reports of people exposed to tofacitinib during early pregnancy have not suggested an increased chance of miscarriage.

Does taking tofacitinib 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 is not known if tofacitinib increases the chance of birth defects above the background risk. Animal studies showed an increase in birth defects with the use of tofacitinib at much higher doses than those used in humans. No increased chance of birth defects has been reported in cases of people exposed to tofacitinib during early pregnancy.

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

Studies have not been done to see if tofacitinib increases the chance of pregnancy-related problems, such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth).

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

Studies have not been done to see if tofacitinib can cause behavior or learning issues for the child.

Breastfeeding while taking tofacitinib:

Tofacitinib has not been well studied for use during breastfeeding. The manufacturer and an expert panel recommend that

breastfeeding be stopped while using tofacitinib and for 18 hours after the last dose. For the extended release form (Xeljanz® XR), they recommend waiting 36 hours after the last dose before breastfeeding again. Be sure to talk to



your

healthcare provider about all your breastfeeding questions.

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

Studies have not been done to see if tofacitinib could affect male fertility (ability to get partner pregnant) or increase the chance of birth defects above the background risk. 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 to view references.

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

Disclaimer: MotherToBaby Fact Sheets are meant for general information purposes and should not replace the advice of your health care provider. MotherToBaby is a service of the non-profit Organization of Teratology Information Specialists (OTIS). OTIS/MotherToBaby encourages inclusive and person-centered language. While our name still contains a reference to mothers, we are updating our resources with more inclusive terms. Use of the term mother or maternal refers to a person who is pregnant. Use of the term father or paternal refers to a person who contributes sperm. Copyright by OTIS, December 1, 2023.