Tofacitinib (Xeljanz®, Xeljanz XR®)

This sheet is about exposure to tofacitinib in pregnancy and while breastfeeding. This information is based on published research studies. 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, ankylosing spondylitis and ulcerative colitis. Some brand names for tofacitinib are Xeljanz® and Xeljanz XR®.

MotherToBaby has fact sheets on rheumatoid arthritis here: https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/, psoriasis here: https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/, ankylosing spondylitis here: https://mothertobaby.org/fact-sheets/ankylosing-spondylitis/ and inflammatory bowel disease here: https://mothertobaby.org/fact-sheets/inflammatory-bowel-disease-pregnancy/.

Tofacitinib has been studied in treating 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 women who are pregnant or breastfeeding if other recommended treatment options are available. However, the National Institutes of Health (NIH) also states that necessary COVID-19 treatments should not be withheld from women 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 women 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 tofacitinib use during early pregnancy have not suggested an increased chance of miscarriage.

Does taking tofacitinib increase the chance of birth defects?

Birth defects can happen in any pregnancy for different reasons. Out of all babies born each year, about 3 out of 100 (3%) will have a birth defect. We look at research studies to try to understand if an exposure, like tofacitinib, might increase the chance of birth defects in a pregnancy.

There are limited studies on the use of tofacitinib in pregnancy. No increased chance of birth defects has been reported when tofacitinib was used 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 can increase 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 increase the chance of behavior or learning issues for the child.

Breastfeeding while taking tofacitinib:

Tofacitinib has not been well studied for use during breastfeeding. In 2 reports of tofacitinib use while breastfeeding, the amount that was found in breast milk was low. Additionally, no side effects were reported in either breastfed infant. There have been no large research studies on the use of tofacitinib in breastfeeding.

The product label for tofacitinib and an expert panel recommends women who are breastfeeding not use this medication during breastfeeding, and that breastfeeding should not resume until 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. This is because there is not enough information available on the use of tofacitinib to know if/how it could affect breastfeeding or a breastfed child. But the benefits of using tofacitinib and breastfeeding might outweigh possible risks. Your healthcare providers can talk with you about using tofacitinib and what treatment is best for you. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

Studies have not been done to see if tofacitinib could affect male fertility (ability to get make healthy sperm) or increase the chance of birth defects. 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.

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