



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Tofacitinib (Xeljanz®)

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. This sheet talks about whether exposure to tofacitinib may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

What is tofacitinib?

Tofacitinib is a prescription medication used to treat moderate to severe rheumatoid arthritis. Tofacitinib is marketed under the brand name Xeljanz®. Xeljanz® is a pill taken by mouth, typically twice a day.

How long does tofacitinib stay in the body? Should I stop taking it before I try to get pregnant??

Individuals break down medicines at different rates. On average it takes only about three hours for one half of the medicine to leave the body. This means most of the medicine will be gone from the body in about a day.

You should not stop taking any medication without first talking with your health care provider. The benefits of taking tofacitinib and treating your autoimmune condition during pregnancy need to be weighed against the possible risks of continuing the medication.

Can taking tofacitinib make it more difficult for me to become pregnant?

Studies on women have not yet been done to see if there is any effect on human fertility.

Can taking tofacitinib during my pregnancy cause pregnancy loss or birth defects?

It is not known whether tofacitinib can cause birth defects. Animal studies showed an increase in birth defects with the use of doses much higher than those used in humans. There are 46 reports of women exposed to tofacitinib mostly during early pregnancy. No increase in pregnancy loss or birth defects was seen. At this point we cannot be sure what, if any, risk there is with the use of tofacitinib in pregnancy.

Can I take tofacitinib while breastfeeding?

Tofacitinib has not been studied for use during breastfeeding. Be sure to talk to your health care provider about all your breastfeeding questions.

What if the father of the baby takes tofacitinib?

There are no studies looking at possible risks to a pregnancy when the father takes tofacitinib. There are 44 four reports of fathers exposed to tofacitinib. No increase in pregnancy loss or birth defects was seen. 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 and Pregnancy at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

MotherToBaby is currently conducting a study looking at autoimmune diseases and the 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/>.

Selected References:

- Merren A, Chen Y, Frazier D, Geier J. 2015. Pregnancy Outcomes in the tofacitinib RA study database through April 2014. Abstract doi 10.1136/annrheumdis-2015-eular.3547.

- Clowse, M., et al. 2016. Pregnancy Outcomes in the Tofacitinib Safety Databases for Rheumatoid Arthritis and Psoriasis. *Drug Saf* 39:755-762,
- Xeljanz® Prescribing Information. Available online at <http://labeling.pfizer.com/ShowLabeling.aspx?id=959> accessed 26 April 2014.

February, 2018