



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

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

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Sarilumab (Kevzara®)

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 sarilumab may increase the risk for birth defects over that background risk. This fact sheet also provides a summary of information for breastfeeding mothers. This information should not take the place of medical care and advice from your health care provider.

What is sarilumab?

Sarilumab is a medication used for the treatment of rheumatoid arthritis (RA) that has not responded to other medications. Sarilumab has been sold under the brand name Kevzara®. Sarilumab is an antibody (a protein made by the body's immune system) that binds and blocks interleukin-6 (a protein that causes inflammation). Sarilumab is used to reduce symptoms and joint damage in persons with RA. Sarilumab is injected under the skin every two weeks.

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

The time that it takes for this medication to leave the body depends upon the dose. It can take up to one or two months for sarilumab to leave the adult body.

Do not stop taking sarilumab without first talking to your healthcare provider. It is important to weigh the benefits of treating RA during pregnancy against the possible risks of taking this medicine. For more information about RA and pregnancy, please see our fact sheet at: <https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/pdf/>.

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

This is not known. Sarilumab did not interfere with the ability to become pregnant when tested in animals, but it is not known if the result from animals applies to humans.

Can taking sarilumab during my pregnancy increase the chance of miscarriage?

This is not known. There are currently no studies looking at whether sarilumab increases the chance for miscarriage in women. Sarilumab did not cause an increase in miscarriage when tested in animals, but it is not known if this result applies to humans.

Can taking sarilumab increase the chance of having a baby with a birth defect?

This is not known. Animal studies by did not find an increase in birth defects but human pregnancy studies have not been done. Antibodies are not expected to cross the placenta in the first trimester of pregnancy.

Can taking sarilumab increase the chance for other pregnancy complications?

This is not known. Based on the structure of sarilumab, more of the medication is thought to reach the pregnancy during the second and especially the third trimester. However, there are currently no studies that have looked at children of mothers who took sarilumab during pregnancy.

Can my baby receive live vaccines before one year of age if I take sarilumab later in pregnancy?

Most vaccines given in the first 6 months of life are noninfectious and can be given to a baby even if sarilumab is present in his/her blood. Noninfectious vaccines are not live vaccines, meaning a person cannot get the infection from the vaccine.

Live vaccines are typically avoided in adults taking sarilumab. Live vaccines usually contain a milder form of the virus or bacteria than what you might be exposed to in the community. Live vaccines always carry a small chance a person could get the infection from the vaccine. The rotavirus vaccine is the only live vaccine given to infants less than

one year of age in the United States in the regular immunization schedule. There is no medical recommendation on whether a baby whose mother took sarilumab during pregnancy should get live vaccines during the first six months of life. Always be sure to let your pediatrician know of any medications or exposures during pregnancy and/or breastfeeding. Your pediatrician can discuss the risks and benefits of live vaccines with you.

Can I take sarilumab while breastfeeding?

There are no studies looking at sarilumab during breastfeeding. Because sarilumab is a large protein, it is thought that only very small amounts could get into the breast milk. Absorption by the baby is also less likely because any of the medicine that reaches the baby is likely to be destroyed in the infant's gastrointestinal system. If the baby is born preterm (prior to 37 weeks), absorption may be higher until his or her system matures. Be sure to talk to your healthcare provider about all your breastfeeding questions.

What if the father of the baby takes sarilumab?

There are no studies looking at this question. 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 at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

Selected References:

- Raimondo et al. 2017. Profile of sarilumab and its potential in the treatment of rheumatoid arthritis. *Drugs Des Devel Ther.* 11:1593-1603.
- Kevzara® (sarilumab) Prescribing Information. 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761037s000lbl.pdf [Accessed May 15, 2018]

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