Sarilumab (Kevzara®)

This sheet talks about using sarilumab in a pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare 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).

I take sarilumab. Can it make it harder for me to become pregnant?
Studies have not been done in women to see if taking sarilumab will make it harder to become pregnant. 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.

I just found out that I am pregnant, should I stop taking sarilumab?
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 any possible concerns 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/.

Does taking sarilumab increase the chance of miscarriage?
Miscarriage can occur in any pregnancy. There are 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 these results apply to humans.

Does taking sarilumab in the first trimester increase the chance of birth defects?
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. There are no human studies looking at whether sarilumab increases birth defects. Animal studies did not find an increase in birth defects.

Could taking sarilumab in the second or third trimester increase the chance for other pregnancy complications?
Based on the structure of sarilumab, more of the medication is thought to reach the pregnancy during the second and especially the third trimester. At this time, there are no studies looking at sarilumab and pregnancy complications. This means it is not known if sarilumab can increase pregnancy complications.

Does taking sarilumab in pregnancy cause long-term problems in behavior or learning for the baby?
There are no studies looking at sarilumab and long-term problems.

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. Let your child’s pediatrician know of any medications or exposures you had during pregnancy and/or breastfeeding. Your pediatrician can discuss the risks and benefits of live vaccines with you.

**Can I breastfeed while taking sarilumab?**

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 medication that reaches the baby is likely to be destroyed in the infant’s gastrointestinal (GI) system. If the baby is born preterm (prior to 37 weeks), absorption may be higher until his or her system matures. If you suspect that the baby has symptoms related to the medication, contact the child’s healthcare provider. Talk to your healthcare provider about all your breastfeeding questions.

**If a man takes sarilumab, could it affect his fertility (ability to get partner pregnant) or increase the chance of birth defects?**

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/.

MotherToBaby is currently conducting a study looking at sarilumab and other 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 visit: https://mothertobaby.org/join-study/.

Please click here for references.