Sarilumab (Kevzara®)

This sheet is about exposure to sarilumab 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 providers.

What is sarilumab?

Sarilumab is a medication that has been used for the treatment of rheumatoid arthritis (RA) and polymyalgia rheumatica (PMR). It has also been used to treat symptoms of severe COVID-19 in hospitalized patients. Sarilumab is a monoclonal antibody (a protein made by the body's immune system) that binds and blocks interleukin-6 (IL-6), a protein that causes inflammation. A brand name for sarilumab is Kevzara®. For more information about RA and pregnancy, please see our fact sheet at https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/.

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 this 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 sarilumab. Can it make it harder for me to get pregnant?

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

Does taking sarilumab increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not been done in humans to see if taking sarilumab during pregnancy can increase the chance of miscarriage.

Does taking sarilumab 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 sarilumab, might increase the chance of birth defects in a pregnancy.

Studies have not been done to see if sarilumab increases the chance for birth defects above the background risk. There is a report of one woman using sarilumab during pregnancy and no birth defects were detected in the child. It is reassuring that sarilumab is not expected to cross the placenta and reach the pregnancy in large amounts during the first trimester, which is the time when a birth defect is most likely to happen.

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

It is not known if sarilumab can increase the chance of pregnancy-related problems such as preterm delivery (birth before week 37 of pregnancy) or low birth weight (weighing less than 5 pounds, 8 ounces [about 2,500 grams] at birth). A small study that included one pregnancy exposed to sarilumab during treatment for COVID-19 suggested a higher risk of preterm delivery. However, COVID-19 is itself associated with preterm delivery, making it hard to know whether the observed risk was due to the infection or sarilumab exposure.

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

Studies have not been done to see if sarilumab can increase the chance of behavior or learning issues for the child. There is a report of one woman using sarilumab during pregnancy and no problems were noted in the child at 6 months of age.

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

Since sarilumab might suppress the immune system of the person taking it, there is a theoretical (not proven) concern that the same thing could happen to the baby if they are exposed during pregnancy. If a person has a weakened immune system, they may be more likely to develop an infection from a live vaccine. Live vaccines contain a small

amount of live virus. Inactivated vaccines do not contain live virus, so they cannot cause the disease they protect against. In the United States, rotavirus is the only live vaccine routinely given in the first year of life. Most people can get inactivated vaccines in the first year of life.

Talk with your child's healthcare provider about your exposure to sarilumab during pregnancy. They can talk with you about the vaccines your child should receive and the best time for your child to receive them.

Breastfeeding while taking sarilumab:

There is very little information on the use of sarilumab during breastfeeding. Because sarilumab is a large protein, only small amounts are expected to pass into breast milk. In one study, a small amount of sarilumab was detected in breast milk. Any medication that enters the milk is likely to be broken down in the baby's stomach and only minimally absorbed. Preterm infants and babies younger than 1 month of age may absorb more of the medication than older infants. Be sure to talk to your healthcare provider about all your breastfeeding questions.

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

Studies have not been done to see if sarilumab can affect male fertility (ability to make healthy sperm) or increase the chance of birth defects. In general, exposures that fathers or sperm donors have are less likely 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.