Belimumab (Benlysta®)

This sheet is about exposure to belimumab in a pregnancy or while breastfeeding. This information is based on available published literature. It should not take the place of medical care and advice from your healthcare provider.

What is belimumab?

Belimumab is a prescription medication used to treat systemic lupus erythematosus (SLE). Belimumab is prescribed to people who have active SLE and are receiving other lupus medications. Belimumab is a type of protein known as a monoclonal antibody and has also been referred to as a "biologic". Belimumab is sold under the brand name Benlysta®. MotherToBaby has a sheet on lupus available at: https://mothertobaby.org/fact-sheets/lupus-pregnancy/.

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 am taking belimumab, but I would like to stop taking it before becoming pregnant. How long does the drug stay in my body?

The time it takes the body to metabolize (to process) medication is not the same for everyone. In healthy adults, it takes up to 4 months, on average, for most of the belimumab to be gone from the body.

I take belimumab. Can it make it harder for me to get pregnant?

Studies have not been done to see if belimumab could make it harder to get pregnant.

Does taking belimumab increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Based on animal studies done by the manufacturer, a case series, and one study in humans, belimumab is not expected to increase the chance of miscarriage. Lupus itself might increase the chance of miscarriage.

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

Animal studies done by the manufacturer (with doses higher than the recommended dose used in people) did not show an increase in birth defects after exposure to belimumab. In humans, 2 case series and 1 study, totaling 77 women, have not found an increased chance for a pattern of birth defects.

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

It is not known if belimumab can cause other pregnancy complications, such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth). One study did not find an increased chance for pregnancy related problems. Active lupus, itself, may increase the chance of pregnancy complications such as preterm delivery and poor growth of the baby.

Does taking belimumab during pregnancy have any effect on my baby after birth?

It is not yet known if belimumab can have an effect on the baby after birth. Monoclonal antibodies, such as belimumab, cross the placenta during the third trimester of pregnancy and in theory might affect the baby's immune system (the system in the body that helps fight off infections). One small study did not find a risk for a weakened immune system in the infant in the days after birth. Animal studies done by the manufacturer showed a weakened immune system in the offspring of animals exposed to belimumab during pregnancy, but these effects went away after 3 to 12 months.

Does taking belimumab in pregnancy affect future behavior or learning for the child?
Studies have not been done to see if belimumab can cause behavior or learning issues for the child.

Can my baby receive live vaccines before one year of age if I take belimumab while pregnant?
Since some biologic medications might suppress the immune system of the adult taking it, there is a theoretical concern that the same thing could happen to the baby if they are exposed during pregnancy. It is not known if exposure to belimumab during pregnancy affects a baby's ability to fight off infection. If someone 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 belimumab 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 belimumab:
Belimumab is a large protein and little of the medication is expected to pass into breast milk. Belimumab is not well absorbed from the gut when swallowed. So any medication that would get into breast milk would be unlikely to enter the baby's system. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

If a man takes belimumab, could it affect fertility or increase the chance of birth defects?
Studies have not been done to see if belimumab could affect a man's fertility (ability to get a woman pregnant) or increase the chance of birth defects. In general, exposures that men 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/.

Help us find answers to common questions!
MotherToBaby is currently conducting a study looking at belimumab use in pregnancy. If you are interested in learning more about this study, please call 1-877-311-8972 or visit https://mothertobaby.org/join-study.

Please click here for references.

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