Belimumab (Benlysta®)

This sheet is about exposure to belimumab in a pregnancy or while breastfeeding. This information 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 who 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 given in a healthcare provider’s office, a hospital, or an infusion center by an administration of the medication directly into a vein (infusion). Belimumab can also be given as an injection under the skin (subcutaneous injection). It is sold under the brand name Benlysta®.

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

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

I just found out I am pregnant. Should I stop taking belimumab?

Talk with your healthcare providers before making any changes to how you take your medication. The benefits of taking belimumab and treating your SLE during pregnancy need to be weighed against the risks of untreated illness. For more information on the effects of SLE during pregnancy, please see the MotherToBaby fact sheet on lupus at: https://mothertobaby.org/fact-sheets/lupus-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?

People eliminate medications at different rate. In healthy adults, it takes up to 4 months, on average, for most of the belimumab to be gone from the body.

Does taking belimumab increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. It is not known if belimumab increases the chance for miscarriage. Animal studies done by the manufacturer did not show an increase in miscarriage after exposure to belimumab. Lupus itself may increase the chance of miscarriage early in pregnancy.

Does taking belimumab increase the chance of birth defects?

Every pregnancy starts with a 3-5% chance of having a birth defect. This is called the background risk. It is not known if belimumab increases the chance for birth defects above the background risk. 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.

Could taking belimumab cause other pregnancy complications?

It is not known if belimumab can cause other pregnancy complications. However, active lupus itself may increase the chance of pregnancy complications such as preterm delivery (delivery before 37 weeks of pregnancy) and growth restriction of the baby.

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

It is not 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 could affect the baby’s immune system (the system in the body that helps fight off infections). Animal studies done by the manufacturer showed a weakened immune system in the offspring of females exposed to belimumab during pregnancy, but these effects went away after 3 to 12 months.

Can my baby receive live vaccines before one year of age if I take belimumab while pregnant?
Most vaccines given in the first 6 months of life are noninfectious and can be given to a baby even if belimumab is present in their blood. Noninfectious vaccines are not live vaccines, meaning a person cannot get the infection from the vaccine. Live vaccines carry a small chance that a person could develop the infection from the vaccine. However, live vaccines usually contain a milder form (attenuated) of the virus or bacteria than what you might be exposed to in the community. Types of live vaccines given in the US include measles-mumps-rubella (MMR), varicella (chicken pox), and rotavirus vaccine. The rotavirus vaccine is the only live vaccine given to infants less than one year of age in the United States. The vaccine series must be started by 15 weeks of age. Rotavirus is one of the leading causes of vomiting and severe diarrhea in children.

It is not known if exposure to belimumab during pregnancy affects a baby’s ability to fight off infection. Some recent research has shown that babies exposed to biologics in pregnancy appear to build antibodies as expected and have the same typical response to vaccines as babies not exposed to these medications.

Talk to your child’s pediatrician about any medications or exposures during pregnancy and/or breastfeeding. They can discuss the risks and benefits of live vaccines with you.

**Can I breastfeed 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, so any medication that would get into breast milk would be unlikely to enter the baby’s system. It is possible babies born before 37 weeks with digestive systems that are not fully developed may absorb more of the medication in breast milk. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

**I take belimumab. Can it make it harder for me to get my partner pregnant or increase the chance of birth defects?**

There are no studies looking at possible risks to a pregnancy when males are exposed to belimumab. In general, exposures that fathers or sperm donors 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/.

Please click here for references.

**Belimumab (Benlysta™) Pregnancy Registry. There is a study looking at belimumab in pregnancy. For more information you can look at their website:** [http://pregnancyregistry.gsk.com/belimumab.html](http://pregnancyregistry.gsk.com/belimumab.html)