



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

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

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Belimumab (Benlysta®)

This sheet talks 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 health care 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). Belimumab is sold under the brand name Benlysta®.

How long does belimumab stay in my system? Should I stop taking it before getting pregnant?

Individuals break down medications in their bodies at different rates. On average, most of the belimumab medication is expected to be gone from a healthy adult's body about 4 months after taking the last dose.

You should not stop taking any medication without first talking with your healthcare provider. The benefits of taking belimumab and treating your SLE during pregnancy need to be weighed against any possible risks of continuing the medication. For more information on the effects of SLE during pregnancy, please see the MotherToBaby fact sheet on lupus in pregnancy at: <https://mothertobaby.org/fact-sheets/lupus-pregnancy/>.

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

This is unknown. Studies on women have not yet been done to see if belimumab could make it harder for a woman to get pregnant.

Does taking belimumab increase the chance for miscarriage?

There is not enough information to know if taking belimumab increases a woman's chance for having a miscarriage. Animal studies done by the manufacturer did not show an increase in miscarriage after exposure to belimumab. However, lupus itself may increase the chance of miscarriage early in pregnancy <https://mothertobaby.org/fact-sheets/lupus-pregnancy/>.

Does taking belimumab increase the chance of having a baby with a birth defect?

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 not enough data on belimumab in pregnancy to know if taking belimumab increases the chance for birth defects when used in pregnancy. Animal studies done by the manufacturer (with doses higher than the recommended dose in people) did not show an increase in birth defects after exposure to belimumab.

Could belimumab cause other pregnancy complications?

There are not enough data on belimumab in pregnancy to know if taking belimumab increases the chance for other pregnancy complications. However, active lupus itself may increase the chance of pregnancy complications such as preterm birth (before 37 weeks) and a smaller baby due to growth restriction.

Can taking belimumab during pregnancy have any effect on my baby after it is born?

There are not enough data on belimumab in pregnancy to know if taking belimumab during pregnancy will have an effect on the baby after it is born. 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 his/her 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.

We don't know if prenatal exposure to belimumab affects a baby's ability to fight off infection. Some recent research has shown that babies exposed to biologics in pregnancy appear to have the same typical response to vaccines as babies not exposed to these medications and build antibodies as expected.

Let your child's 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 breastfeed my baby if I am taking belimumab?

There is no information on use of belimumab during breastfeeding. 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 that premature 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.

What if the baby's father takes belimumab?

There are no studies looking at possible risks to a pregnancy when the father takes belimumab. 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 and Pregnancy at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

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>

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