



by the Organization of Teratology Information Specialists (OTIS)

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Benralizumab (Fasenra®)

This sheet talks about exposure to benralizumab in pregnancy and while breastfeeding. This information should not take the place of medical care and advice from your healthcare provider.

What is benralizumab?

Benralizumab is a medication used to treat patients who have severe eosinophilic asthma. Benralizumab is a monoclonal antibody, also referred to as a 'biologic'. It is given by an injection under the skin and is sold under the brand name Fasenra®.

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

Studies have not been done to see if benralizumab could make it harder for a woman to get pregnant.

I just found out that I am pregnant. Should I stop taking benralizumab?

Talk with your healthcare providers before making any changes to this medication. They can go over your options and talk about the risks and benefits of treating or not treating your condition. Untreated asthma increases the chance for complications for both the mother and the baby. For more information about asthma in pregnancy, please see the MotherToBaby fact sheet at https://mothertobaby.org/fact-sheets/asthma-and-pregnancy/pdf/.

Does taking benralizumab increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. Studies have not been done to see if benralizumab increases the chance for miscarriage.

Does taking benralizumab 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 exposure to benralizumab during pregnancy.

Animal studies done by the manufacturer did not show an increase in birth defects with exposure to benralizumab.

Could taking benralizumab in the second or third trimester cause other pregnancy complications?

It is not known if benralizumab can cause pregnancy complications. There are no human studies looking at exposure to benralizumab during pregnancy.

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

There is not enough information to know if taking benralizumab during pregnancy will have an effect on the baby after it is born. Monoclonal antibodies, such as benralizumab, cross the placenta during the third trimester of pregnancy and, in theory, could affect the baby's immune system (the body's ability to fight off infections). Animal studies done by the manufacturer did not show weakened immune systems in the offspring of females exposed to benralizumab during pregnancy.

Does taking benralizumab in pregnancy cause long-term problems in behavior or learning for the baby?

It is not known if benralizumab can cause long-term problems in behavior or learning.

Can my baby receive live vaccines before one year of age if I take benralizumab while pregnant?

Most vaccines given in the first 6 months of life are noninfectious and can be given to a baby even if

benralizumab is present in his/her blood. Noninfectious vaccines are not live vaccines, meaning a person cannot get the infection from the vaccine.

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. Live vaccines given in the newborn period should be avoided, if possible, in the first year of life in case the child's immune system does not respond to the vaccine normally.

Types of live vaccines given in the United States include measles-mumps-rubella (MMR), varicella (chicken pox) and rotavirus vaccines. The rotavirus vaccine is the only live vaccine that is routinely recommended for infants less than one year of age in the United States.

Always be sure to let your 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 benralizumab?

No information is available on the use of benralizumab during breastfeeding. Benralizumab is a very large protein, so very little, if any, is likely to get into breast milk. In addition, benralizumab is poorly absorbed from the gut. So if any medication does get into breast milk, it is unlikely that any of the medication would enter the baby's system. It is possible that premature babies (born before 37 weeks gestation) with digestive systems that are not fully developed would be able to 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 benralizumab?

There are no studies looking at possible risks to a pregnancy when the father takes benralizumab. 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/.

MotherToBaby is currently conducting a study looking at asthma and the medications used to treat asthma in pregnancy. If you would like to learn more about this study, please call 1-877-311-8972 or visit https://mothertobaby.org/join-study/.

Selected References

• Fasenra® Prescribing Information. Available online at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761070s000lbl.pdf. Accessed on July 24th, 2019.

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