

Benralizumab (Fasenra®)

This sheet is 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 monoclonal antibody that belongs to the group of medications known as biologics. It is given by an injection under the skin (subcutaneous). Benralizumab has been used to treat patients with severe eosinophilic asthma. It is sold under the brand name Fasenra®.

Sometimes when people 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.

Untreated asthma increases the chance for complications for both the person who is pregnant and the pregnancy. For more information about asthma, please see the MotherToBaby fact sheet at <https://mothertobaby.org/fact-sheets/asthma-and-pregnancy/>.

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

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

Does taking benralizumab increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not been done to see if benralizumab increases the chance of miscarriage.

Does taking benralizumab increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. Animal studies done by the manufacturer did not show an increase in birth defects after exposure to benralizumab in pregnancy.

There are no human studies looking at use of benralizumab during pregnancy. It was reported that a person with hypereosinophilic syndrome who became pregnant while receiving benralizumab through a clinical trial delivered a healthy baby.

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

Studies have not been done to see if benralizumab increases the chance for pregnancy-related problems such as preterm delivery (birth before week 37) or low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth).

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

Studies have not been done to see if benralizumab can cause behavior or learning issues for the child.

Can taking benralizumab during pregnancy have any effects on my baby after birth?

It is not known if benralizumab can have an effect on a baby after birth. 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 offspring that were exposed to benralizumab during pregnancy.

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

Since benralizumab may suppress the immune system of the person taking it, there is a theoretical concern that the same thing could happen to the baby if they are exposed during pregnancy. Live vaccines contain a small amount of

live virus and carry a small chance a person could get the infection from the vaccine. If someone has a weakened immune system, they may be more likely to develop an infection from the vaccine.

Most vaccines given in the first 6 months of life are inactivated vaccines. Inactivated vaccines do not contain live virus, so they cannot cause the disease they protect against. Live vaccines are usually avoided in the first year of life, if possible, in case the child's immune system does not respond to the vaccine as expected. In the United States, rotavirus is the only live vaccine routinely given in the first year of life. It is the best way to protect infants against rotavirus.

There is research that suggests that babies exposed to biologics in pregnancy build antibodies as expected and have the same typical response to vaccines as babies not exposed to these medications. Talk with your child's healthcare provider and your child's pediatrician about your exposure to benralizumab 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 benralizumab:

Benralizumab has not been well studied for use during breastfeeding. It is a very large protein, so it is likely that little medication would pass into breast milk. Benralizumab is not well absorbed by the gut, so any of the medication that gets into breast milk would be unlikely to enter the baby's system. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a male takes benralizumab, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?

Studies have not been done to see if benralizumab could affect male fertility or increase the chance of birth defects above the background risk. 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/>.

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/>.

Please click here for references.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at [MotherToBaby.org](https://mothertobaby.org).

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