Benralizumab (Fasenra®)

This sheet is about exposure to benralizumab in pregnancy and while breastfeeding. This information is based on available research studies. It should not take the place of medical care and advice from your healthcare provider.

What is benralizumab?

Benralizumab is a monoclonal antibody (man-made proteins that work like natural antibodies in the body to boost the immune system). It belongs to a group of medications known as biologics and 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 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 your medication. Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

Asthma that is untreated or not well controlled can increase the chance of complications for both the woman 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?

Studies have not been done to see 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 can increase the chance of miscarriage.

Does taking benralizumab 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 benralizumab, can increase the chance of birth defects in a pregnancy.

Studies looking at use of benralizumab during human pregnancy have not been done. There is 1 report of a woman with hypereosinophilic syndrome, who became pregnant while receiving benralizumab and delivered a healthy baby. Animal studies did not show an increase in birth defects after exposure to benralizumab during pregnancy.

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

Studies have not been done to see if benralizumab can increase the chance of 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).

There is a theoretical (not proven) concern that monoclonal antibodies could affect a baby's immune system (the body's ability to fight off infections). Animal studies have not reported any changes to the immune systems after exposure to benralizumab during pregnancy.

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

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

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

Since benralizumab might suppress the immune system of the person taking it, there is a theoretical (not proven) 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, so there is a small chance that a person could get the infection from the vaccine. If someone has a weakened immune system, they might 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 any live virus, so they cannot cause the disease they protect against. If possible, live vaccines are avoided in the first year of life, in case the child's immune system does not respond to the vaccine. In the United States, rotavirus is the only live vaccine routinely given in the first year of life, because it is the best way to protect infants against rotavirus.

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 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 expected to pass into breast milk in small amounts. Benralizumab is not well absorbed by the gut, so any of the medication that gets into breast milk would be unlikely to enter the child's system. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes benralizumab, could it affect fertility or increase the chance of birth defects?

Studies have not been done to see if benralizumab could affect men's fertility (ability to get a woman pregnant) or increase the chance of birth defects. 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 relating to 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.

Disclaimer: MotherToBaby Fact Sheets are meant for general information purposes and should not replace the advice of your health care provider. MotherToBaby is a service of the non-profit Organization of Teratology Information Specialists (OTIS). Copyright by OTIS, December 1, 2024.