Ofatumumab (Kesimpta®, Arzerra®)

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

What is ofatumumab?

Ofatumumab is a monoclonal anti-CD20 antibody that works by lowering the amount of B cells in a person's body. B cells are a type of white blood cell that makes antibodies. Ofatumumab has been used to treat adults with relapsing forms of multiple sclerosis (MS). MotherToBaby has a fact sheet on multiple sclerosis here: https://mothertobaby.org/fact-sheets/multiple-sclerosis/. Ofatumumab has also been used to treat chronic lymphocytic leukemia. Some brand names for ofatumumab are Kesimpta® and Arzerra®.

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.

I am taking ofatumumab, but I would like to stop taking it before becoming pregnant. How long does the drug stay in my body?

People eliminate medication at different rates. In healthy adults, it takes up to 96 days (a little over 3 months), on average, for most of the ofatumumab to be gone from the body.

The product label for ofatumumab recommends that females who can get pregnant should use an effective method of birth control while taking this medication and to continue to use birth control for 6 months after stopping ofatumumab.

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

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

Does taking ofatumumab increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies have not been done in humans to see if ofatumumab can increase the chance for miscarriage. Miscarriage has been reported in people exposed to ofatumumab during pregnancy.

Does taking ofatumumab 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 ofatumumab, might increase the chance of birth defects in a pregnancy.

There is limited published information describing people who were exposed to ofatumumab during pregnancy. No birth defects were reported in over 20 pregnancies exposed to ofatumumab. Animal studies done in monkeys have not reported an increased chance of birth defects.

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

Studies have not been done to see if ofatumumab 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).

Animal studies have reported lower B-cell counts and reduced antibody response in offspring exposed to ofatumumab during pregnancy. Having a low number of B cells can increase the chance for infections.

It is not known if using ofatumumab in pregnancy could increase the chance of infections in infants. In over 20

pregnancies exposed to ofatumumab, there were no reports of B-cell depletion, problems with antibodies or blood (immunoglobulin/hematological abnormalities), or serious infections in live births.

Since some biologic medications might 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. If someone has a weakened immune system they may be more likely to develop an infection from a live vaccine. Live vaccines contain a small amount of live virus. Inactivated vaccines do not contain live virus. In the United States, rotavirus is the only live vaccine routinely given in the first year of life.

The product label for this drug recommends that infants who were exposed to ofatumumab during pregnancy should have their B-cell levels tested before receiving live vaccines. This is because having low B-cells may increase the chance of infection from live vaccines. Inactivated (not live) vaccines may be given to babies on schedule before B-cell levels are back to normal. However, ofatumumab may change how well inactivated vaccines work. Talk with your child's healthcare provider about your exposure to ofatumumab during pregnancy. They can talk with you about the vaccines your child should receive and the best time for your child to receive them.

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

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

Breastfeeding while taking ofatumumab:

There is limited information on the use of ofatumumab while breastfeeding. Ofatumumab is a large protein molecule, which means the amount that passes into breastmilk is expected to be low. Ofatumumab would likely break down in the infant's intestinal tract, and the amount of medication absorbed into the infant is expected to be low. In one study where 12 mothers received ofatumumab, the amount of ofatumumab in their breast milk was small and no health effects were reported among the nursing infants. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

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

Studies have not been done to see if ofatumumab 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 the risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Help us find answers to common questions!

MotherToBaby is currently conducting a study looking at ofatumumab and other medications used to treat multiple sclerosis in pregnancy. If you are interested in learning 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.

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