

Ofatumumab (Kesimpta® , Arzerra®)

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

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). It has also been used to treat chronic lymphocytic leukemia. Some brand names for ofatumumab are Kesimpta® and Arzerra®.

MotherToBaby has a fact sheet on multiple sclerosis here: <https://mothertobaby.org/fact-sheets/multiple-sclerosis/>.

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 getting 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 increases the chance for miscarriage. Miscarriage has been reported in people exposed to ofatumumab during pregnancy.

Does taking ofatumumab 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. Studies have not been done in humans to see if ofatumumab increases the chance for birth defects. 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 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.

Since ofatumumab 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. If someone has a weakened immune system, they may be more likely to develop an infection from the vaccine. Inactivated vaccines do not contain live virus, so they cannot cause the disease they protect against. In the

United States, rotavirus is the only live vaccine routinely given in the first year of life.

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.

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 no 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 is likely to be broken down in the infant's intestinal tract, and the amount of medication absorbed by the infant is expected to be low. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

If a male takes ofatumumab, could it affect fertility (ability to get partner pregnant) 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/>.

MotherToBaby is currently conducting a study looking at multiple sclerosis and medications used to treat it 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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