Abatacept (Orencia®)

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

What is abatacept?

Abatacept is a medication that has been used to treat rheumatoid arthritis (RA), juvenile rheumatoid arthritis (JRA), and psoriatic arthritis (PsA). It has also been used to treat COVID-19 in some hospitalized patients. It works by lowering the activity of T cells (part of the body's immune system) to help reduce inflammation or swelling. It can be given through a vein in the arm (infusion) or by a shot under the skin. It is sold under the brand name Orencia®.

To learn more about rheumatoid arthritis and psoriatic arthritis, please see the MotherToBaby fact sheets at https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/ and https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/. To learn more about COVID-19, please see the MotherToBaby fact sheet at https://mothertobaby.org/fact-sheets/covid-19/.

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.

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

The time it takes the body to metabolize (process) medication is not the same for everyone. In healthy adults, it takes up to 10 weeks, on average, for most of the abatacept to be gone from the body.

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

Studies have not been done in humans to see if taking abatacept can make it harder to get pregnant. In experimental animal studies, problems with fertility (ability to get pregnant) were not reported

Does taking abatacept increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. The manufacturer did not find a higher chance of miscarriage among 151 women who used abatacept in pregnancy. In another study with 64 pregnancies exposed to abatacept, there was a higher rate of miscarriage than would be expected. However, the study did not compare this finding against other possible contributing factors, so conclusions cannot be drawn from this report. Because miscarriage can happen for many reasons, it is hard to know whether a medication, the condition being treated, or other factors such as age or health are the cause.

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

Animal studies done by the manufacturer did not show an increased chance of birth defects when abatacept was used in pregnancy. Abatacept has not been well studied in human pregnancy. However, published information collected on over 200 pregnancies did not find a pattern of birth defects associated with abatacept use in pregnancy. There is also a case report of a woman with active rheumatoid arthritis who became pregnant while using abatacept, with her last dose just after the fourth week of pregnancy. She delivered a healthy infant that was also reported to be doing well at a 3.5-year follow-up visit. Based on limited information, an increased risk for birth defects is not expected with exposure to abatacept.

Does taking abatacept in pregnancy increase the chance of other pregnancy related

problems?
Studies have not been done to see if abatacept can increase the chance of other 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 abatacept in pregnancy affect future behavior or learning for the child?
Studies have not been done to see if abatacept can increase the chance for behavior or learning issues for the child.

Breastfeeding while taking abatacept:
Abatacept passes into breast milk in small amounts because it is a large molecule. Also, abatacept is poorly absorbed from the gut, so it is unlikely that any of the medication the baby swallowed in the breast milk would be absorbed into the baby's system. In limited reports, a child exposed to abatacept through breast milk did not experience any side effects. Be sure to talk to your healthcare provider about all your breastfeeding questions.

If a man takes abatacept, could it affect fertility or increase the chance of birth defects?
Studies have not been done to see if abatacept could affect men's fertility (ability to make healthy sperm). The manufacturer reported on 10 males who were taking abatacept when their partners became pregnant and did not find a greater chance for birth defects. In general, men's exposures are less likely to increase risks to a pregnancy. For more general information, please see the MotherToBaby fact sheet Paternal Exposures (https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/).

MotherToBaby is currently conducting a study looking at abatacept and other medications used to treat autoimmune diseases 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.

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