



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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Abatacept (Orencia®)

In every pregnancy, a woman starts out with a 3-5% chance of having a baby with a birth defect. This is called her background risk. This sheet talks about whether exposure to abatacept may increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

What is abatacept?

Abatacept is a prescription medication used to treat rheumatoid arthritis (RA) and juvenile rheumatoid arthritis (JRA). Abatacept is a protein that suppresses overly active T cells, which are important cells in the body that help fight infection but that also cause inflammation. Abatacept can lead to a decrease in symptoms and joint damage in patients with rheumatoid arthritis. It can be given in a health care provider's office by intravenous infusion (through a vein in the arm) every 4 weeks, or once a week at home with a shot under the skin. It is sold under the brand name Orencia®.

How long does abatacept stay in the body? Should I stop taking it before I try to get pregnant?

Individuals break down medicines at different rates. The average time it takes for one half of the medicine to leave the body is about 14 days. This means that about 10 weeks (or 2 and ½ months) after taking the last dose of abatacept, most of the medicine will be gone from the body.

You should not stop taking any medication without first talking with your health care provider. The benefits of taking abatacept and treating your autoimmune condition during pregnancy need to be weighed against the possible risks of continuing the medication.

Can taking abatacept make it more difficult for me to become pregnant?

Animal studies done by the manufacturer did not find that fertility was lowered with the use of abatacept in pregnancy. There have been no studies done in humans to see if abatacept has any effect on human fertility. At this time, it is not known if taking abatacept would make it more difficult for a woman to get pregnant.

Can taking abatacept during my pregnancy cause birth defects?

Animal studies done by the manufacturer did not show an increased chance for birth defects when abatacept was used in pregnancy. However, there have been no studies reporting the use of abatacept in human pregnancy. There is a single case report of a woman with active rheumatoid arthritis who became pregnant while using abatacept, with her last dose just after fourth week of pregnancy. She delivered a healthy infant that was also reported to be fine at a 3.5-year follow-up visit. At this time, it is not known if the use of abatacept in pregnancy can increase the chance for birth defects.

Abatacept is a large protein. Because of this, it is thought that a very limited amount of medicine can cross the placenta (the blood connection a pregnant woman shares with her baby) and reach the developing baby during the first trimester. However, without information about the use of abatacept in human pregnancy, the risk to the developing baby is unknown.

Can I take abatacept while breastfeeding?

There have been no studies looking at the use of abatacept during breastfeeding. Because abatacept is a very large protein, it is not likely that very much of the medication would be able to pass into breast milk. Also, abatacept is poorly absorbed from the gut, so it is unlikely that any of the medication that gets into breast milk would enter the baby's system. It is possible that premature babies (born before 37 weeks gestation) with digestive systems that are not fully developed may be able to absorb more of the medication in breast milk. Be sure to talk to your health care

provider about all your choices for breastfeeding.

What if the father of the baby takes abatacept?

There are no studies looking at possible risks to a pregnancy when the father takes abatacept. In general, exposures that fathers have are unlikely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures and Pregnancy at <http://www.mothersbaby.org/files/paternal.pdf>.

MotherToBaby is currently conducting a study looking at abatacept and other medications used to treat autoimmune diseases in pregnancy. If you are interested in taking part in this study, please call 1-877-311-8972.

Selected References:

- Makol A, et al. 2011. Rheumatoid arthritis and pregnancy: safety considerations in pharmacological management. *Drugs*. 22;71(15):1973-87.
- Ojeda-Urbe M, et al. 2013. Exposure to abatacept or rituximab in the first trimester of pregnancy in three women with autoimmune diseases. *Clin Rheumatol*. 32(5): 695-700.
- Orenzia Prescribing Information. Available online at http://packageinserts.bms.com/pi/pi_orencia.pdf. Accessed 27 Jul 2012.
- Ostensen M and Förger F. 2011. Treatment with biologics of pregnant patients with rheumatic diseases. *Curr Opin Rheumatol*. 23(3):293-8.
- Partlett R and Roussou E. 2011. The treatment of rheumatoid arthritis during pregnancy. *Rheumatol Int*. 31(4):445-9.
- Pham T., et al. 2012. Abatacept therapy and safety management. *Joint Bone Spine* 79 Suppl 1:3-84.

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