



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

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

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Apremilast (Otezla®)

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 apremilast 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 apremilast?

Apremilast is a prescription medication that helps treat the symptoms of moderate to severe psoriasis and psoriatic arthritis. It is thought to work inside of cells to prevent inflammation. Apremilast is marketed under the brand name Otezla®. It is a pill taken by mouth, typically twice a day.

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

Individuals break down medicines at different rates. On average it takes only about 6-9 hours for one half of the medicine to leave the body. This means most of the medicine will be gone from the body two days after taking the last dose.

You should not stop taking any medication without first talking with your health care provider. The benefits of taking apremilast and treating your autoimmune condition during pregnancy need to be weighed against the possible risks of continuing the medication. For more information on the effects of psoriasis during pregnancy, please see the MotherToBaby fact sheet Psoriasis and Pregnancy at <http://www.mothersbaby.org/fact-sheets/psoriasis-and-pregnancy/pdf/>.

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

This is not clear. Studies on women have not yet been done to see if there is any effect on a woman's ability to become pregnant. However, animal studies have not shown a negative effect on fertility.

Can taking apremilast during my pregnancy cause pregnancy loss?

The risk of pregnancy loss due to exposure to apremilast is unknown. Some animal studies performed by the manufacturer found an increase in miscarriage at doses higher than those given to humans. However, other similar animal studies have not shown an increase in pregnancy loss. No human studies of pregnancy loss and exposure to apremilast have been found.

Can taking apremilast during my pregnancy cause birth defects?

Unknown. It is not known whether apremilast can cause birth defects. The animal studies done by the manufacturer did not find an increased risk of birth defects with exposure to apremilast. We have been unable to locate any human studies looking at the risk for birth defects. The animal studies suggest that exposure to apremilast would not be a significant cause of birth defects; however, further study is needed.

Can I take apremilast while breastfeeding?

Apremilast has not been studied for use during breastfeeding in humans. Animal studies showed that Apremilast was excreted in breast milk but the levels were low. Be sure to talk to your health care provider about all your breastfeeding questions.

What if the father of the baby takes apremilast?

There are no studies looking at possible risks to a pregnancy when the father takes apremilast. 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 <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

MotherToBaby is currently conducting a study looking at apremilast 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 or sign up at <https://mothertobaby.org/join-study/>.

References:

- Celgene Corporation. 2015. Otezla product label. Accessed March 2016 <http://www.otezla.com/otezla-prescribing-information.pdf>

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