

Apremilast (Otezla®)

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

What is apremilast?

Apremilast is a prescription medication that helps treat the symptoms of moderate to severe psoriasis and psoriatic arthritis, plaque psoriasis, and the oral (mouth) ulcers associated with Behcet's disease. Apremilast is marketed under the brand name Otezla®. For information on psoriasis and psoriatic arthritis please see the MotherToBaby fact sheet at: <https://mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/>.

Sometimes when people find out they are pregnant, they think about changing how they take their medication, or stopping their medication altogether. Apremilast has not been well studied with use in a pregnancy or while breastfeeding. 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 take apremilast. Can it make it harder for me to get pregnant?

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

Does taking apremilast increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. Apremilast has not been well studied with use in pregnancy. The chance of miscarriage after exposure to apremilast is unknown. Animal studies found a greater chance for miscarriage when doses higher than those given to humans was used. No human studies on apremilast and miscarriage have been found.

Does taking apremilast increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a baby with a birth defect. This is called the background risk. It is not known whether apremilast increases the chance of birth defects. The animal studies done by the manufacturer did not find an increased chance of birth defects. While the animal data would suggest a low chance of harm, we have been unable to locate studies on the use of apremilast in human pregnancies.

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

Studies in humans have not been done to see if apremilast 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). Studies in animals found a higher chance of low birth weight offspring at levels higher than the human dose.

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

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

Breastfeeding while taking apremilast:

Apremilast has not been studied for use during breastfeeding in humans. Animal studies showed that apremilast can enter breast milk at low levels. The product label for apremilast recommends people who are breastfeeding not use this medication. But, the benefit of using apremilast may outweigh possible risks. Your healthcare providers can talk with you about using apremilast and what treatment is best for you. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

If a male takes apremilast, could it affect fertility (ability to get partner pregnant) or increase the chance of birth defects?

Studies have not been done to see if apremilast could affect male fertility or increase the chance of birth defects. In general, exposures that fathers or sperm donors have are unlikely to increase risks to a pregnancy. For more

information, please see the MotherToBaby fact sheet on Paternal Exposures at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

MotherToBaby is currently conducting a study looking at autoimmune diseases and the medications used to treat autoimmune diseases in pregnancy. If you would like to learn more, please call 1-877-311-8972 or visit <https://mothertobaby.org/join-study/>.

Please click [here](#) to view references.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at [MotherToBaby.org](https://mothertobaby.org).

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