Apremilast (Otezla®)

This sheet is about exposure to apremilast 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 apremilast?

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

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

It is not known if apremilast can make it harder to get pregnant. However, animal studies have not shown a negative effect on fertility.

Does taking apremilast increase the chance of miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies in humans have not been done to see if apremilast can increase the chance of miscarriage. Animal studies found a greater chance of miscarriage with doses of apremilast that are higher than what is used in humans.

Does taking apremilast 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 apremilast, might increase the chance of birth defects in a pregnancy. Studies in humans have not been done to see if apremilast can increase the chance of birth defects. Animal studies did not find an increased chance of birth defects.

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

Studies in humans have not been done to see if apremilast can increase the chance of pregnancy-related problems such as preterm delivery (birth before week 37 of pregnancy) or low birth weight (weighing less than 5 pounds, 8 ounces [2,500 grams] at birth). Animal studies found a higher chance of low-birth-weight offspring with doses of apremilast that are higher than what is used in humans.

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

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

Breastfeeding while taking apremilast:

There is no information about whether apremilast passes into human breast milk, how it may affect a breastfeeding baby, or whether it affects milk production. Apremilast was found in the milk of nursing mice, so it may also be present in human milk. The benefits of using apremilast and breastfeeding might 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 your breastfeeding questions.

If a man takes apremilast, could it affect fertility or increase the chance of birth defects?

Studies have not been done to see if apremilast could affect a man's fertility (ability to make healthy sperm) or increase the chance of birth defects. In general, exposures that fathers or sperm donors have are less likely to increase risks to a pregnancy. For more information, please see the MotherToBaby fact sheet Paternal Exposures at

https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Please click here for references.

Questions? Call 866.626.6847 | Text 855.999.3525 | Email or Chat at MotherToBaby.org.

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