Apremilast (Otezla®)

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

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 people 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 increases the chance of miscarriage. Animal studies found a greater chance of miscarriage with higher doses of apremilast than what is used in humans.

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. Studies in humans have not been done to see if apremilast increases 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 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). Animal studies found a higher chance of low birth weight offspring with higher doses of apremilast 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 cause behavior or learning issues for the child.

Breastfeeding while taking apremilast:

Apremilast has not been studied in humans for use while breastfeeding. Animal studies showed that apremilast gets into breast milk in small amounts. 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 your breastfeeding questions.

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

Studies have not been done to see if apremilast could affect male fertility (ability to get partner pregnant) or increase the chance of birth defects above the background risk. 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 Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.
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/.

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

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