Apremilast (Otezl®)

This sheet talks about exposure to apremilast in a 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. It is thought to work inside of cells to prevent inflammation. Apremilast is marketed under the brand name Otezl®. It is a pill taken by mouth, typically twice a day.

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

This is not clear. Studies on women have not 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.

I just found out I am pregnant. Should I stop taking apremilast?

You should not stop taking this medication without first talking with your healthcare provider. The benefits of taking apremilast and treating your autoimmune condition during pregnancy need to be weighed against any possible risks of continuing the medication. For more information on the effects of psoriasis during pregnancy, please see the MotherToBaby fact sheet at [https://www.mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/pdf/](https://www.mothertobaby.org/fact-sheets/psoriasis-and-pregnancy/pdf/).

Does taking apremilast increase the chance for miscarriage?

Miscarriage can occur in any pregnancy. The chance of miscarriage after 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 on apremilast and miscarriage have been found.

Can taking apremilast during my pregnancy cause birth defects?

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. It is not known whether apremilast can cause birth defects. The animal studies done by the manufacturer did not find an increased chance of birth defects with exposure to apremilast. We have been unable to locate 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.

Can I breastfeed while taking apremilast?

Apremilast has not been studied for use during breastfeeding in humans. Animal studies showed that apremilast was excreted into breast milk but the levels were low. Talk to your healthcare provider about all of your breastfeeding questions.

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

References:
  https://www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/otezla/otezla_pi_english.ashx

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