Mycophenolate (Cellcept®)

This sheet is about exposure to mycophenolate 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 mycophenolate?

Mycophenolate is a medication that has been used to treat some autoimmune conditions like rheumatoid arthritis and lupus. Mycophenolate may also be taken to help prevent the body from rejecting an organ, such as a kidney, after a transplant. Mycophenolate works by lowering the immune system (the body's defense system against substances and germs that could be harmful). Mycophenolate is sold under the brand name Cellcept®. A similar medication called mycophenolic acid is sold under the brand name Myfortic®.

For more information about rheumatoid arthritis and lupus, please see the MotherToBaby fact sheets at https://mothertobaby.org/fact-sheets/rheumatoid-arthritis/ and https://mothertobaby.org/fact-sheets/lupus-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.

The product label for mycophenolate recommends women who are pregnant not use this medication during pregnancy. Your healthcare provider can talk with you about using and what treatment is best for you.

Your healthcare providers can talk with you about the benefits of treating your condition and the risks of untreated illness during pregnancy.

I am taking mycophenolate, but I would like to stop taking it before getting pregnant. How long does the drug stay in my body?

The time it takes the body to metabolize (to process) medication is not the same for everyone. In healthy non-pregnant adults, it takes up to one week, on average, for most of the mycophenolate to be gone from the body.

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

It is not known if mycophenolate can make it harder to get pregnant.

The U.S. Food and Drug Administration (FDA) requires that women who may become pregnant participate in a mycophenolate education program before they start taking the medication. Healthcare providers who prescribe mycophenolate must also participate in the program. The program requires having a negative pregnancy test before starting mycophenolate, and another negative pregnancy test eight to ten days after treatment begins. The program also recommends using effective birth control to prevent pregnancy while taking mycophenolate. Birth control should continue for 6 weeks after stopping mycophenolate. It is important to know that mycophenolate might make hormonal birth control methods, like birth control pills, not work as well to prevent pregnancy.

Does taking mycophenolate increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Taking mycophenolate in pregnancy can increase the chance of miscarriage. One report suggests the chance for miscarriage with mycophenolate use during pregnancy may be close to 50% (1 in every 2 pregnancies). Since some of the conditions that mycophenolate is used to treat can also increase the chance of miscarriage, it is hard to know if the medication, the medical condition, or other factors are the cause of a miscarriage.

Does taking mycophenolate 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 mycophenolate, might increase the chance of birth defects in a pregnancy.

Taking mycophenolate during pregnancy might increase the chance of birth defects. A pattern of birth defects has been reported that includes unusually small or absent ears, eyes, and/or jaw; heart defects, cleft lip and/or palate (openings in the lip or the roof of the mouth), and others. Affected children might have only one birth defect or a combination of these birth defects. Not all children exposed to mycophenolate during pregnancy will have a birth defect.

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

There is limited information on whether mycophenolate can increase the chance of other pregnancy-related problems, such as preterm delivery (birth before week 37) and low birth weight (weighing less than 5 pounds, 8 ounces [2500 grams] at birth). One small study reported an increased chance of preterm delivery and low birth weight with mycophenolate exposure during pregnancy.

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

It is not known if mycophenolate can increase the chance for behavior or learning issues for the child.

What screenings or tests are available to see if my pregnancy has birth defects or other issues?

Prenatal ultrasounds can be used to screen for some birth defects, such as defects of the ears, eyes, jaw, heart, lip, and palate. Ultrasound can also be used to watch the growth of the pregnancy. Talk with your healthcare provider about any prenatal screenings or testing that are available to you. There are no tests available during pregnancy that can tell how much effect there could be on future behavior or learning.

Breastfeeding while taking mycophenolate:

It is not clear how much mycophenolate gets into breast milk. Limited reports of infants that have been exposed to mycophenolate through breast milk have not reported harmful effects.

The product label for mycophenolate recommends women who are breastfeeding use caution when using this medication during breastfeeding. This is because there is not enough information available on the use of mycophenolate to know if/how it could affect breastfeeding. But the benefits of using mycophenolate and breastfeeding might outweigh possible risks. Be sure to talk to your healthcare provider about all of your breastfeeding questions.

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

Studies have not been done to see if mycophenolate could affect male fertility (ability to make healthy sperm). Three studies looking at 356 infants born to men taking mycophenolate around the time of conception found no increase in birth defects. Another report including 255 children born to men taking mycophenolate also showed no increase in miscarriage or birth defects.

Due to theoretical concern (and not proven risks), some healthcare providers may recommend that men taking mycophenolate wait at least three months after stopping treatment before trying to conceive a pregnancy. In general, men's exposures are less likely to increase risks to a pregnancy. For more general information, please see the MotherToBaby fact sheet Paternal Exposures at https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/.

Help us find answers to common questions!

MotherToBaby is currently conducting a study looking at lupus and medications used to treat lupus 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.

Please click here for references.

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

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