Mycophenolate (Cellcept®)

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

What is mycophenolate?

Mycophenolate is a medication that lowers the function of the body’s immune system. Your immune system helps your body fight infection. Mycophenolate 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. It is sold under the brand name Cellcept®. A related medication called mycophenolic acid is sold under the brand name of Myfortic®.

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

People eliminate medication at different rates. In healthy 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 people who may become pregnant and healthcare providers to participate in a mycophenolate education program. This program includes confirmation of a negative pregnancy test before starting mycophenolate and a negative pregnancy test at eight to ten days after treatment begins. The program also recommends using effective birth control while taking mycophenolate. Birth control should continue for 6 weeks after stopping mycophenolate. It is important to know that mycophenolate may reduce the ability of hormonal birth control methods, like birth control pills, to prevent pregnancy.

Does taking mycophenolate increase the chance for miscarriage?

Miscarriage is common and can occur in any pregnancy for many different reasons. Studies suggest there is an increased chance of miscarriage if mycophenolate is taken during pregnancy. People who have had organ transplants and/or have autoimmune conditions like rheumatoid arthritis and lupus also have an increased chance for miscarriage based on their medical condition, so it is hard to know the exact risks due to mycophenolate. One report suggests the chance for miscarriage with mycophenolate use during pregnancy may be close to 50% (1 in every 2 pregnancies).

Does taking mycophenolate increase the chance of birth defects?

Every pregnancy starts out with a 3-5% chance of having a birth defect. This is called the background risk. A pattern of birth defects has been reported with the use of mycophenolate during pregnancy. There may be one defect, or a combination of birth defects. Possible birth defects include 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. Not all babies with this exposure will have a birth defect.

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

Based on the studies reviewed, it is not known if mycophenolate can cause other 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).
Based on the studies reviewed, it is not known if mycophenolate increases the chance for behavior or learning issues.

**Breastfeeding while taking mycophenolate:**

Information on the use of mycophenolate while breastfeeding is very limited. There are reports of a few infants that have been exposed to mycophenolate through breastmilk. No harmful effects have been reported. Be sure talk to your healthcare provider about all of your breastfeeding questions.

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

Three studies looking at 356 infants born to males taking mycophenolate around the time of conception found no increase in the chance for birth defects. Another report including 255 children born to males taking mycophenolate also showed no increase in the chance of miscarriage or birth defects.

Due to theoretical concern (and not proven risks), some healthcare providers may recommend that males taking mycophenolate wait at least three months after stopping treatment before trying to conceive a pregnancy. In general, exposures that fathers or sperm donors have are unlikely to increase the 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 lupus and the medications used to treat lupus in pregnancy. If you would like to learn more, please call 1-877-311-8972 or sign up at https://mothertobaby.org/join-study.

Please click here for references.