



MotherToBaby

Medications & More During Pregnancy & Breastfeeding  
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

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## Mycophenolate

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. This sheet talks about whether exposure to mycophenolate might increase the risk for birth defects over that background risk. This information should not take the place of medical care and advice from your health care provider.

### ***What is mycophenolate?***

Mycophenolate is a prescription medication that lowers the function of the body's immune system. Your immune system helps your body fight infection. Some autoimmune, or overactive immune system conditions like rheumatoid arthritis and lupus have been treated with mycophenolate. Mycophenolate may also be taken to help prevent the body from rejecting an organ, such as a kidney, after a transplant.

Mycophenolate can be taken orally (by mouth) as capsules, tablets, or as a liquid. It can also be given directly into your vein (IV) at your healthcare provider's office. Mycophenolate is sold under the brand name of Cellcept® and a related medication called mycophenolic acid is sold under the brand name of Myfortic®.

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

Studies have not focused on the possible affects mycophenolate may have on a woman's fertility. Studies suggest that mycophenolate can increase the risk of miscarriage and birth defects, so it is not recommended during pregnancy. It's possible that there may be a time when a doctor and pregnant woman decide that using this medication during pregnancy is necessary and may outweigh possible risks to the baby.

The Food and Drug Administration requires women and health care providers to participate in a mycophenolate education program. This program includes confirmation of a negative pregnancy test before starting mycophenolate and 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 methods, like birth control pills, to prevent pregnancy.

Women planning pregnancy are advised to take folic acid prior to pregnancy to reduce the chance of having a baby with a brain and/or spinal cord defect.

### ***How long does mycophenolate stay in the body? Should I stop taking it before I try to get pregnant?***

People break down medication at different rates. In healthy non-pregnant adults, it takes an average of one week for most of the mycophenolate to be gone from your body.

If you are planning pregnancy, talk to your doctor about when you should stop this medication and treatment options. It is not recommended to get pregnant while on this medication because of the risk of birth defects.

### ***I just found out that I am pregnant. Should I stop taking mycophenolate?***

Do not make any changes to your medication without first talking to your healthcare provider. If you suspect you are pregnant or you test positive for pregnancy while taking mycophenolate, call your healthcare provider right away. Your healthcare provider can help you decide if you should continue taking mycophenolate or if other medications may be more appropriate to treat your condition. Health care providers can also offer more frequent ultrasound examinations to closely monitor your pregnancy.

### ***Does taking mycophenolate during my pregnancy increase the chance of miscarriage?***

Yes, studies suggest there is an increased chance of miscarriage if mycophenolate is taken during pregnancy.

Women 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

difficult to estimate the exact risks due to mycophenolate. The chance for miscarriage with mycophenolate use during pregnancy might be close to 50% (1 in every 2 pregnancies).

***Does taking mycophenolate increase the chance of having a baby with a birth defect?***

Yes. A pattern of birth defects has been seen with the use of mycophenolate during pregnancy. Small studies suggest the risk for mycophenolate related birth defects could affect 25%, or 1 in 4 babies. Not all babies with this exposure will have a birth defect. Babies who do have mycophenolate birth defects could have one defect, or a combination of birth defects. The possible defects have included 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 other birth defects. Studies have not been done to assess possible problems mycophenolate may cause with a babies immune system or problems with leaning.

***Can I breastfeed my baby if I am taking mycophenolate?***

There is very limited information for mycophenolate use while breastfeeding. There is a report of seven infants who were breastfed without problems while their mothers were taking mycophenolate, however, no studies have been done to determine the amount of mycophenolate that can enter breastmilk. It is very important to speak with your healthcare provider regarding breastfeeding. If your baby has symptoms that concern you, contact the child's healthcare provider right away.

***What if the baby's father takes mycophenolate?***

In general, a father's exposures are unlikely to increase risks to a pregnancy. Two studies looking at about 350 infants fathered by men taking mycophenolate around the time of conception found no increase in birth defects. However, due to theoretical concern rather than actual risks, some health care providers may recommend that men taking mycophenolate wait at least three months after stopping treatment before trying to conceive. For more general information, please see the MotherToBaby fact sheet titled "Paternal Exposures and Pregnancy" at <https://mothertobaby.org/fact-sheets/paternal-exposures-pregnancy/pdf/>.

**Please click here for references.**

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