Mycophenolate

This sheet talks 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 prescription medication that lowers the function of the body’s immune system. Your immune system helps your body fight infection. Some autoimmune 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 become pregnant?
Studies have not focused on the possible effects mycophenolate may have on a woman’s fertility.

The U.S. Food and Drug Administration (FDA) requires women 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.

Women planning pregnancy are advised to take folic acid before 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 healthcare provider about when you should stop this medication and your 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?
Talk with your healthcare providers before making any changes to your medication(s). 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. Healthcare providers can also offer more frequent ultrasound examinations to closely monitor your pregnancy.

Does taking mycophenolate increase the chance of miscarriage?
Miscarriage can occur in any pregnancy. 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 know 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 birth defects?
In every pregnancy, a woman starts with a 3-5% chance of having a baby with a birth defect. This is called her background risk. 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 birth defects related to mycophenolate 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.

Could taking mycophenolate cause other pregnancy complications?
There are no studies on the effect of taking mycophenolate during the second and third trimesters.

Does taking mycophenolate in pregnancy cause long-term problems in behavior of learning for the baby?
There are no studies on the possible long-term effects of mycophenolate on the developing baby.

Can I breastfeed while 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. No studies have been done to determine the amount of mycophenolate that can enter breastmilk. Be sure 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?
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 healthcare providers may recommend that men taking mycophenolate wait at least three months after stopping treatment before trying to conceive. In general, exposures that fathers have are unlikely 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/pdf/.

Please click here for references.