

MYCOPHENOLATE PREGNANCY REGISTRY FREQUENTLY ASKED QUESTIONS FOR PATIENTS

What is the Mycophenolate Pregnancy Registry?

The Registry collects information about pregnancies that occur during treatment with mycophenolate or within 6 weeks after stopping.

Why should I take part in the Mycophenolate Pregnancy Registry?

The information you provide to the Registry will help us better understand the effects of mycophenolate in pregnancy.

When you take part in the Registry, you provide important information that may help you and other women who take mycophenolate during their pregnancies. Women taking mycophenolate while they are pregnant have a higher risk of miscarriage in the first 3 months. There is also a higher risk that the baby will have birth defects.

Who can be in the Mycophenolate Pregnancy Registry?

1. All females who get pregnant while taking mycophenolate and
2. All females who get pregnant within 6 weeks after stopping treatment with mycophenolate

These medicines contain mycophenolate:

- CellCept® (mycophenolate mofetil)
- Myfortic® (mycophenolic acid)
- MYHIBBIN™ (mycophenolate mofetil oral suspension)
- Generic formulations of mycophenolate mofetil
- Generic formulations for mycophenolic acid

Tell your doctor right away if you get pregnant. Your doctor should report your pregnancy to the Registry. We encourage you to take part in the Registry. The information you provide to the Registry will help us better understand the effects of mycophenolate in pregnancy. All the information you provide will be kept private.

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What will I need to do to take part in the Mycophenolate Pregnancy Registry?

There are a few simple steps to take.

1. Tell your doctor if you get pregnant

- The Registry will contact you after speaking with your doctor

2. Complete an *Informed Consent* form

- The *Informed Consent* form will be mailed to you
- The form tells you what to expect with the Registry. It tells you what your rights are
- By signing, you allow the Registry to ask you questions about your health and your baby's health. The Registry will also ask for information from your doctors

3. Answer the Registry's questions about your health and your baby's health

- After the first 3 months of pregnancy
- 2 more times during the next 6 months of pregnancy
- At the time of expected delivery
- When your baby is 2 months, 6 months, and 1 year

4. Let the Registry know if your contact information changes

- The Registry relies on your information to contact you. If your contact information changes, please call **1-800-617-8191**

What are my rights if I take part in the Mycophenolate Pregnancy Registry?

1. You can quit at any time.
2. Your privacy is protected.

What if I do not want to take part in the Mycophenolate Pregnancy Registry?

You only take part in the Registry if you want to do it. If you decide not to participate, it will not change your medical care.

How can I get more information?

- Call **1-800-617-8191** and choose "Mycophenolate Pregnancy Registry" from the menu
- For more information about Mycophenolate REMS, visit **www.MycophenolateREMS.com**