



# PATIENT INFORMATION BROCHURE

What you need to know about mycophenolate use and pregnancy risk

## What is my role in the Mycophenolate REMS?

<b>1</b>	Talk with your doctor about the risks of mycophenolate
<b>2</b>	Talk with your doctor about acceptable birth control and use it during your entire treatment with mycophenolate and for 6 weeks after you stop taking mycophenolate
<b>3</b>	Complete a pregnancy test before starting mycophenolate and another pregnancy test 8 to 10 days later to determine if you are pregnant. Repeat pregnancy tests during routine follow-up visits with your doctor
<b>4</b>	If you get pregnant while taking mycophenolate or within 6 weeks after you stop, call your doctor right away. Do not stop taking mycophenolate prior to speaking with your doctor

To learn more about the serious risks of taking Mycophenolate, please see the *Medication Guide*, which can be found at [www.MycophenolateREMS.com](http://www.MycophenolateREMS.com)

# MYCOPHENOLATE AND INCREASED RISKS OF MISCARRIAGE AND BIRTH DEFECTS

**There are increased risks of miscarriage and birth defects with use of mycophenolate. As a patient, here is what you should know.**

## WHAT ARE THE RISKS WITH MYCOPHENOLATE?



- Higher risk of losing a pregnancy (miscarriage) during the first 3 months
- Higher risk that the baby may be born with these birth defects:
  - ▶ Defects of the ears
  - ▶ Cleft lip or cleft palate
  - ▶ Defects of the arms, legs, heart, esophagus, kidney, and nervous system
- These are not all of the serious risks of taking mycophenolate. Please read the Medication Guide, which can be found at [MycophenolateREMS.com](http://MycophenolateREMS.com) to learn about all of the risks of taking mycophenolate.

## WHAT IS THE MYCOPHENOLATE REMS?

- The Mycophenolate Risk Evaluation and Mitigation Strategy (REMS) is a program to tell patients and healthcare providers about the higher risk of pregnancy loss (miscarriage) and birth defects with the use of mycophenolate.
- This program is required by the Food and Drug Administration (FDA) to help prevent miscarriages and birth defects.
- Females who can get pregnant and are taking mycophenolate should participate in the Mycophenolate REMS.
- Mycophenolate is available by prescription as:
  - ▶ CellCept® (mycophenolate mofetil), Myfortic® (mycophenolic acid), MYHIBBIN™ (mycophenolate mofetil oral suspension), Generic mycophenolate mofetil, Generic mycophenolic acid.

## WHAT DO I NEED TO KNOW ABOUT PREGNANCY PREVENTION?

- Talk with your doctor about birth control and pregnancy planning. Unless you choose not to have sexual intercourse with a man at any time (abstinence), you must always use acceptable birth control.
  - ▶ During your entire treatment with mycophenolate
  - ▶ For 6 weeks after you stop taking mycophenolate
- If you are thinking about having a baby, tell your doctor right away and do not stop taking mycophenolate before speaking to your doctor.
  - ▶ In some cases, you and your doctor may decide that your medicine is more important to your health than the increased risks to your unborn baby.
- If you get pregnant while you are taking mycophenolate or within 6 weeks after you stop taking mycophenolate, tell your doctor right away and do not stop taking mycophenolate before speaking to your doctor.

## DATA INSIGHTS

In December 2006, the National Transplantation Pregnancy Registry (NTPR) published data from prospective cases where 24 female transplant patients taking mycophenolate reported 33 pregnancies\*. Of these pregnancies, there were:

- 15 spontaneous abortions (45%)
- 18 live-born infants

Four of the 18 live-born infants had birth defects (22%).

Of the 77 females who took mycophenolate during pregnancy †:

- 25 had spontaneous abortions
- 14 had a fetus or infant-with defects.

While available data are limited, birth defects occur in approximately 20% of live-born infants exposed to mycophenolate during pregnancy. First trimester pregnancy loss rates are approximately 45%\*†.

\*Sifontis NM, et al. Pregnancy outcomes in solid organ transplant recipients with exposure to mycophenolate mofetil or sirolimus. *Transplantation*. 2006;82:1698-1702.

†Prescribing Information for mycophenolate.

To learn more about all the risks of taking mycophenolate, please see the Medication guide, which can be found at [MycophenolateREMS.com](http://MycophenolateREMS.com)

# MYCOPHENOLATE AND INCREASED RISKS OF MISCARRIAGE AND BIRTH DEFECTS

***If you are a girl or woman who can get pregnant, you should participate in the Mycophenolate REMS while you are taking mycophenolate. To participate follow these three steps.***

## 1 TALK WITH YOUR DOCTOR

- Talk with your doctor about mycophenolate use and risk of miscarriage or birth defects.

## 2 CHOOSE A BIRTH CONTROL OPTION

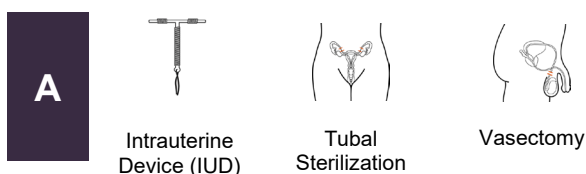
- Choosing birth control is very personal. Talk with your doctor or obstetrician/gynecologist to decide what is best for you. Unless you choose not to have sexual intercourse with a man at any time (abstinence), you must use acceptable birth control for your entire treatment with mycophenolate and for 6 weeks after you stop taking mycophenolate.
- Unless you use an intrauterine device (IUD), have had sterilization surgery (had your tubes tied or blocked), or if your partner has had a vasectomy, you may need to use more than one method of birth control at the same time.
- Mycophenolate could make hormone methods of birth control not work as well.
  - ▶ It is possible that birth control pills may not work as well when you take mycophenolate and you could become pregnant.
  - ▶ It is possible that other hormone methods (like the patch, the ring, the shot, and the implant) may also not work as well when you take mycophenolate and you could become pregnant.
  - ▶ It is important that a barrier method of birth control, like a condom, is also used with any hormone method of birth control.

## ACCEPTABLE BIRTH CONTROL OPTIONS

Talk with your doctor and pick from the following birth control options during treatment with mycophenolate.

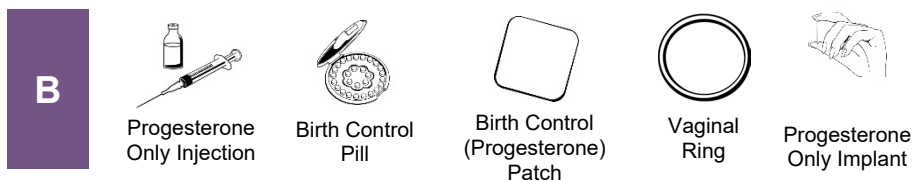
### Option 1 | Use Method Alone

- Pick one item from (A)
  - ▶ **Most effective:** Less than 1 pregnancy per 100 women in one year



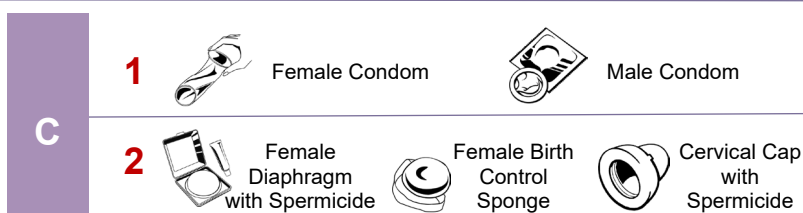
### Option 2 | Use Hormone & Barrier

- Pick one item from (B) **and** one item from (C1) or (C2) shown below
  - ▶ 4-7 pregnancies per 100 women in one year



### Option 3 | Use Two Barriers

- Pick one item from (C1) **and** one from (C2)
  - ▶ **Least effective:** 13 or more pregnancies per 100 women in one year



# MYCOPHENOLATE AND INCREASED RISKS OF MISCARRIAGE AND BIRTH DEFECTS

## 3 GET A PREGNANCY TEST

- You should have a pregnancy test immediately before starting mycophenolate and another pregnancy test 8 to 10 days later.
  - ▶ Your doctor should give you a pregnancy test during routine follow-up visits.
  - ▶ Be sure to talk to your doctor about the results of all of your pregnancy tests.

### IMPORTANT INFORMATION

- If you are thinking about having a baby, talk with your doctor right away. Your doctor will help you decide if other medicines other than mycophenolate may be right for you.
- If you get pregnant while you are taking mycophenolate or within 6 weeks after you stop, contact your doctor right away and do not stop taking mycophenolate before speaking to your doctor.
  - ▶ Your doctor will talk with you about taking part in the Mycophenolate Pregnancy Registry and you should report your pregnancy to the Registry by:
    - Calling 1-800-617-8191 and choosing “Mycophenolate Pregnancy Registry” from the menu options **or**
    - Visiting [MycophenolateREMS.com](https://MycophenolateREMS.com)
  - ▶ After enrollment in the registry, you will be asked to provide informed consent and medical release. Your doctor can review these forms with you.

## RESOURCES FOR YOU

There are many resources to help you get the information you need about the Mycophenolate REMS.

- **Medication Guide for mycophenolate**
  - ▶ Gives you important safety information you need to know about your medicine.
- **Your doctor or other healthcare provider**
- **[MycophenolateREMS.com](https://MycophenolateREMS.com)**
  - ▶ Provides access to all Mycophenolate REMS resources and materials.
- **Mycophenolate Pregnancy Registry**
  - ▶ Collects information about pregnancies that occur during treatment with mycophenolate or within 6 weeks after stopping. You can contact the Registry by calling 1-800-617-8191 or by visiting [MycophenolateREMS.com](https://MycophenolateREMS.com)
- **Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients**
  - ▶ Provides answers to frequently asked questions about the Registry. You can get this from your healthcare provider or by visiting: [MycophenolateREMS.com](https://MycophenolateREMS.com)
  - ▶ Birth Control: [plannedparenthood.org](https://plannedparenthood.org)
  - ▶ Birth Control: [FDA.gov](https://FDA.gov)