



This brochure tells you about:

- the higher risks of miscarriage and birth defects with mycophenolate
- your role in the Mycophenolate REMS program
- your birth control options while taking mycophenolate

# MYCOPHENOLATE REMS

MYCOPHENOLATE-RELATED RISK OF MISCARRIAGE AND BIRTH DEFECTS

**Mycophenolate REMS:**  
**What You Need To Know About Mycophenolate**

For complete safety information, please see the *Medication Guide*, which can be found at [www.MycophenolateREMS.com](http://www.MycophenolateREMS.com).



**OVERVIEW  
FOR PATIENTS**

# MYCOPHENOLATE REMS

MYCOPHENOLATE-RELATED RISK OF MISCARRIAGE AND BIRTH DEFECTS

## Table of Contents

Welcome to Mycophenolate REMS.....	3
Increased Risks of Miscarriage and Birth Defects with Mycophenolate Use.....	4
What You Need to Know About Pregnancy Prevention.....	5
Your Role.....	6
Your Birth Control Options.....	7
Reporting Your Pregnancy.....	9
Important Resources.....	10
Other Resources.....	11



## Welcome to Mycophenolate REMS

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Mycophenolate REMS (**R**isk **E**valuation and **M**itigation **S**trategy) is a program to tell patients and healthcare providers about the higher risk of miscarriage and birth defects with the use of mycophenolate. This program is required by the Food and Drug Administration (FDA). Females who can get pregnant and are taking mycophenolate should participate in the Mycophenolate REMS program.

This brochure tells you what you need to know about taking mycophenolate. It explains

- the higher risks of loss of a pregnancy (miscarriage) during the first three months and birth defects with use of mycophenolate,
- your role in the Mycophenolate REMS
- your acceptable birth control options.

Please read all of the information in this brochure. Talk with your doctor if you have questions.

These medicines contain mycophenolate:

- CellCept® (mycophenolate mofetil)
- Myfortic® (mycophenolic acid)
- Generic mycophenolate mofetil
- Generic mycophenolic acid

For complete safety information, please the *Medication Guide*, which can be found at [www.MycophenolateREMS.com](http://www.MycophenolateREMS.com)

## Increased Risks of Miscarriage and Birth Defects with Mycophenolate Use

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The Mycophenolate REMS program focuses on these risks:

- 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 [www.MycophenolateREMS.com](http://www.MycophenolateREMS.com) to learn about all of the risks of taking mycophenolate.

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## What You Need to Know about Pregnancy Prevention

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If you are a girl or woman who can get pregnant, your doctor will talk with you about the risks of mycophenolate during pregnancy. Talk with your doctor about birth control and pregnancy planning.

### **You must always use acceptable birth control**

- During your entire treatment with mycophenolate
- For 6 weeks after you stop taking mycophenolate

Unless you choose not to have sexual intercourse with a man at any time (abstinence), you must always use acceptable birth control.

### **It is important to talk with your doctor about the best forms of birth control for you.**

The table on page 8 lists your options for birth control during treatment with mycophenolate.

### **If you are thinking about having a baby**

- Tell your doctor right away
- Do not stop taking mycophenolate on your own
- In some cases, you and your doctor may decide that your medicine is more important to your health than the possible risks to your unborn baby

### **If you get pregnant while you are taking mycophenolate or within 6 weeks after you stop**

- Tell your doctor right away
- Do not stop taking mycophenolate

## Your Role

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If you are a girl or woman who can get pregnant, you should take part in the Mycophenolate REMS while you are taking mycophenolate.

Steps you need to take:

1. Talk with your doctor about mycophenolate use and risk of miscarriage or birth defects.
2. Sign the *Mycophenolate REMS Patient-Prescriber Acknowledgment Form*.
3. Decide with your doctor what birth control methods are right for you.
4. You should have one pregnancy test immediately before starting mycophenolate and another pregnancy test 8 to 10 days later.
  - Pregnancy tests should be repeated during routine follow-up visits with your doctor.
  - Talk to your doctor about the results of all of your pregnancy tests.
5. If you are thinking about having a baby, talk with your doctor right away. Your doctor will decide if other medicines to prevent rejection may be right for you.
6. If you get pregnant while you are taking mycophenolate or within 6 weeks after you stop, tell your doctor right away.
7. If you get pregnant while you are taking mycophenolate, join in the Mycophenolate Pregnancy Registry. The purpose of this registry is to gather information about the health of you and your baby.

## Your Birth Control Options

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Choosing birth control is very personal. This brochure gives you information on birth control methods you can use while taking mycophenolate. This information should be used along with your doctor's medical advice. After you read this brochure, talk with your doctor or obstetrician/gynecologist. Then, you and your doctor can decide what is best for you.

### **You must always use acceptable birth control**

- During your entire treatment with mycophenolate
- For 6 weeks after you stop taking mycophenolate

Unless you choose not to have sexual intercourse with a man at any time (abstinence), you must always use acceptable birth control.

### **You may need to use more than one method of birth control at the same time.**

If you use an **intrauterine device (IUD)**, had **sterilization surgery** (had your tubes tied or blocked), or if your partner has had a **vasectomy**, you do not need to use a second form of birth control.

### **Mycophenolate could make hormone methods of birth control not work as well.**

- Studies show that mycophenolate lowers blood levels of certain hormones in the **birth control pill**.
- 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 and you could become pregnant.
- It is important that a **barrier method** of birth control is **also used** with any hormone method of birth control.

The table on page 8 lists your options for birth control during treatment with mycophenolate.

## Your Birth Control Options (cont'd)

The table below lists your options for birth control during treatment with mycophenolate. Pick from the following birth control options:

Acceptable Contraception Methods			
<b>Option 1</b>  <b>Methods to Use Alone</b>	<ul style="list-style-type: none"> <li>■ Intrauterine devices (IUDs)</li> <li>■ Tubal sterilization</li> <li>■ Patient's partner had a vasectomy</li> </ul>		
OR			
<b>Option 2</b>  <b>Choose One Hormone Method AND One Barrier Method</b>	<b>Hormone Methods</b> choose 1		<b>Barrier Methods</b> choose 1
	<b>Estrogen and Progesterone</b> <ul style="list-style-type: none"> <li>■ Oral contraceptive pill</li> <li>■ Transdermal patch</li> <li>■ Vaginal ring</li> </ul> <b>Progesterone-only</b> <ul style="list-style-type: none"> <li>■ Injection</li> <li>■ Implant</li> </ul>	AND	<ul style="list-style-type: none"> <li>■ Diaphragm with spermicide</li> <li>■ Cervical cap with spermicide</li> <li>■ Contraceptive sponge</li> <li>■ Male condom</li> <li>■ Female condom</li> </ul>
OR			
<b>Option 3</b>  <b>Choose One Barrier Method From Each Column (<i>must choose two methods</i>)</b>	<b>Barrier Methods</b> choose 1		<b>Barrier Methods</b> choose 1
	<ul style="list-style-type: none"> <li>■ Diaphragm with spermicide</li> <li>■ Cervical cap with spermicide</li> <li>■ Contraceptive sponge</li> </ul>	AND	<ul style="list-style-type: none"> <li>■ Male condom</li> <li>■ Female condom</li> </ul>

## Reporting Your Pregnancy

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If you get pregnant while taking mycophenolate or within 6 weeks after you stop, call your doctor right away. Do not stop taking your mycophenolate. Your doctor will talk with you about taking part in the Mycophenolate Pregnancy Registry.

You should report your pregnancy to the Registry:

- Call **1-800-617-8191** and choose “Mycophenolate Pregnancy Registry” from the menu, or
- Visit **[www.MycophenolatePregnancyRegistry.com](http://www.MycophenolatePregnancyRegistry.com)**
- Upon enrollment in the registry, patients will be asked to provide informed consent and medical release.

## Important Resources

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

- ***Mycophenolate REMS Patient Brochure: What You Need to Know about Mycophenolate*** (this brochure)
- ***Mycophenolate REMS Patient-Prescriber Acknowledgment Form***  
After a discussion with your doctor about mycophenolate use and risk of miscarriage or birth defects, both of you sign this form.
- **Medication Guide for mycophenolate**  
Gives you important safety information you need to know about your medicine
- **Your doctor or other healthcare provider**
- **Mycophenolate REMS website:**  
**[www.MycophenolateREMS.com](http://www.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 **[www.MycophenolatePregnancyRegistry.com](http://www.MycophenolatePregnancyRegistry.com)**
- ***Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients***  
Provides answers to frequently asked questions about the Registry. You can obtain this from your healthcare provider or by visiting: **[www.MycophenolateREMS.com](http://www.MycophenolateREMS.com)**

## Other Resources

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### For more information about birth control\*

- Association of Reproductive Health Professionals:  
[www.arhp.org](http://www.arhp.org)
- Planned Parenthood: [www.plannedparenthood.org](http://www.plannedparenthood.org)

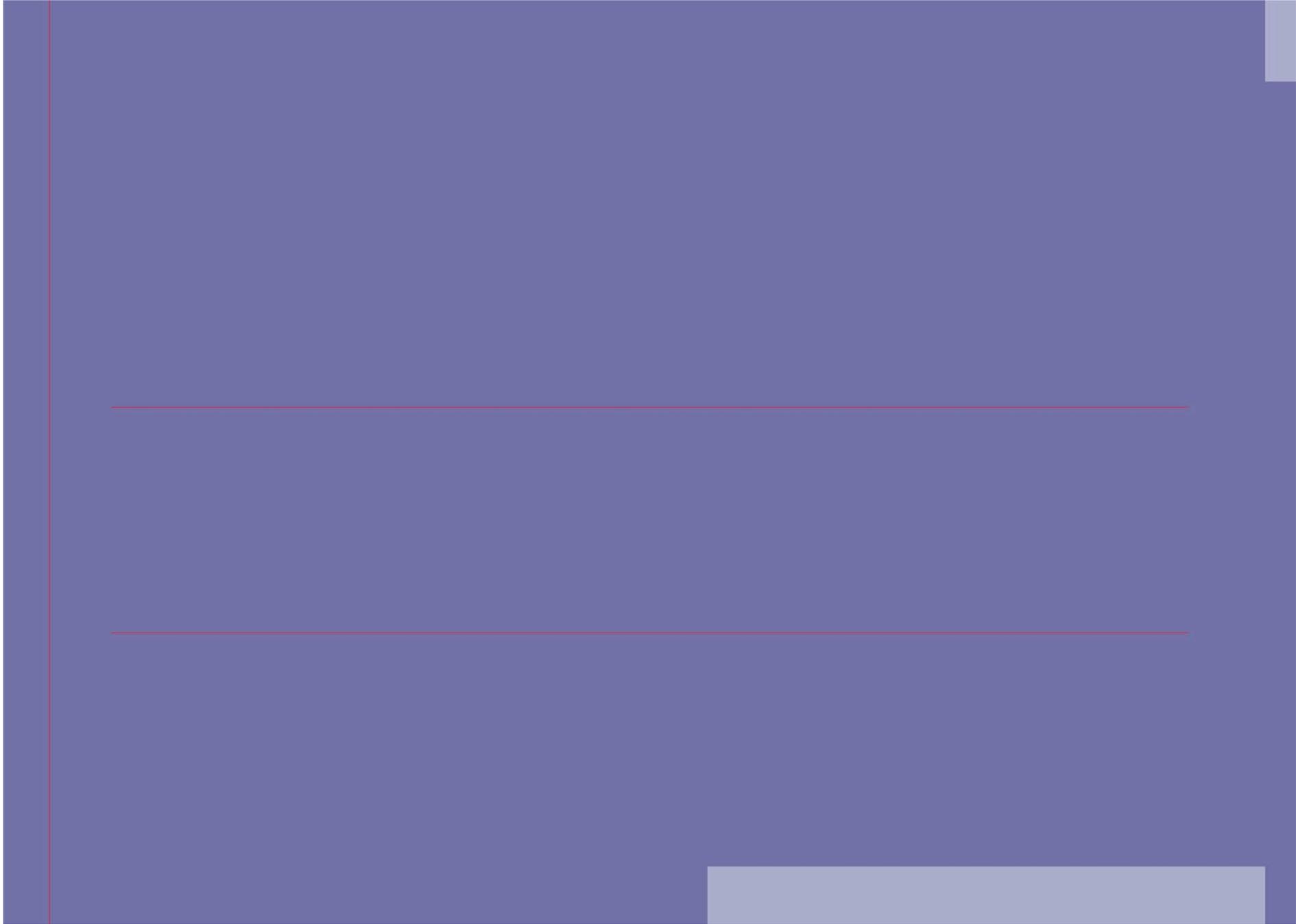
### For emergency birth control\*

- Call your doctor or pharmacy

### For more information about Mycophenolate REMS

- Read the *Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate* (this brochure)
- Talk with your doctor
- Visit the Mycophenolate REMS Web site:  
[www.MycophenolateREMS.com](http://www.MycophenolateREMS.com)
- Call 1-800-617-8191

\*Mycophenolate REMS is neither affiliated with nor an endorser of these organizations. The information provided by Mycophenolate REMS or these organizations is meant for informational purposes only, and is not intended to replace your doctor's medical advice.





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