





MYCOPHENOLATE REMS

MYCOPHENOLATE-RELATED RISK OF MISCARRIAGE AND BIRTH DEFECTS



MYCOPHENOLATE REMS

MYCOPHENOLATE-RELATED RISK OF MISCARRIAGE AND BIRTH DEFECTS

OVERVIEW & YOUR BIRTH CONTROL OPTIONS

For complete safety information, please see the *Medication Guide*, which can be found at www.MycophenolateREMS.com.



**OVERVIEW
FOR PATIENTS**

MYCOPHENOLATE REMS

MYCOPHENOLATE-RELATED RISK OF MISCARRIAGE AND BIRTH DEFECTS

Table of Contents

Welcome to Mycophenolate REMS	3
What You Need to Know	4
Your Role	5
Your Birth Control Options	6
Reporting Your Pregnancy	8
Important Resources	9
Other Resources	10



GLUE STRIP

GLUE STRIP



Welcome to Mycophenolate REMS

Females who take mycophenolate and can get pregnant should participate in Mycophenolate REMS (Risk Evaluation and Mitigation Strategy). Mycophenolate REMS has been designed to tell you about the risks of taking mycophenolate.

Females 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.

These medicines contain mycophenolate:

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

This booklet, the *Mycophenolate REMS Overview & Your Birth Control Options*, tells you what you need to know about Mycophenolate REMS. It explains how it works and what your role is.

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

For complete safety information, please see the *Medication Guide*, which can be found at www.MycophenolateREMS.com.

What You Need to Know

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 7 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.

Your Role

If you are a girl or woman who can get pregnant, you should take part in 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 *Patient-Prescriber Acknowledgment Form*.
3. Decide with your doctor what birth control method(s) is/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.
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, participate in the Mycophenolate Pregnancy Registry. The information you provide helps patients and doctors understand the effects of mycophenolate during pregnancy.

Your Birth Control Options

Choosing birth control is very personal. This booklet 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 booklet, 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 reduce the effectiveness of hormonal methods of birth control

- Hormone methods of birth control must be used with a barrier method because studies show that mycophenolate decreases blood levels of certain hormones in the **oral contraceptive pill**. It is possible that mycophenolate could reduce the effectiveness of the oral contraceptive pill
- The effectiveness of other hormone methods (like the **patch**, the **ring**, the **shot**, and the **implant**) may also be reduced while you are taking mycophenolate

The table on page 7 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			
Option 1 Methods to Use Alone	<ul style="list-style-type: none"> ■ Intrauterine devices (IUDs) ■ Tubal sterilization ■ Patient's partner had a vasectomy 		
	OR		
Option 2 Choose One Hormone Method AND One Barrier Method	Hormone Methods choose 1		Barrier Methods choose 1
	Estrogen and Progesterone <ul style="list-style-type: none"> ■ Oral contraceptive pill ■ Transdermal patch ■ Vaginal ring Progesterone-only <ul style="list-style-type: none"> ■ Injection ■ Implant 	AND	<ul style="list-style-type: none"> ■ Diaphragm with spermicide ■ Cervical cap with spermicide ■ Contraceptive sponge ■ Male condom ■ Female condom
OR			
Option 3 Choose One Barrier Method From Each Column (<i>must choose two methods</i>)	Barrier Methods choose 1		Barrier Methods choose 1
	<ul style="list-style-type: none"> ■ Diaphragm with spermicide ■ Cervical cap with spermicide ■ Contraceptive sponge 	AND	<ul style="list-style-type: none"> ■ Male condom ■ Female condom

Reporting Your Pregnancy

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.

Your doctor should report pregnancies to the Registry. If you would like to report a pregnancy to the Registry yourself:

- Call **1-800-617-8191** and choose “Mycophenolate Pregnancy Registry” from the menu, or
- Visit **www.MycophenolatePregnancyRegistry.com**

Important Resources

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

- ***Mycophenolate REMS Overview & Your Birth Control Options*** (this booklet)
- ***Patient-Prescriber Acknowledgment Form***
After a discussion with your doctor about mycophenolate use and risk of miscarriage or birth defects, both of you will sign this form. It is included with this booklet
- ***Medication Guide for mycophenolate***
Gives you important safety information you need to know about your medicine
- **Your doctor**
- **Mycophenolate REMS Web site: 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**
- ***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**

Other Resources

For more information about birth control*

- Association of Reproductive Health Professionals:
www.arhp.org
- Planned Parenthood:
www.plannedparenthood.org

For emergency birth control*

- Call your doctor or pharmacy
- Emergency Contraception Hotline:
1-888-NOT-2-LATE (1-888-668-2528)

For more information about Mycophenolate REMS

- Read *Mycophenolate REMS Overview & Your Birth Control Options* (this booklet)
- Talk with your doctor
- Visit the Mycophenolate REMS Web site:
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.