

Initial REMS Approval: 09/25/2012
Most Recent Modification: 11/2015

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

Single Shared System for Mycophenolate

I. GOALS

The goal of the Mycophenolate REMS is to mitigate the risk of embryofetal toxicity associated with use of mycophenolate during pregnancy by:

1. Educating healthcare providers on the following:
 - The increased risks of first trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy.
 - The need to counsel females of reproductive potential on the importance of pregnancy prevention and planning when taking mycophenolate.
 - The need to report pregnancies to the Mycophenolate Pregnancy Registry.
2. Informing females of reproductive potential who are prescribed mycophenolate about:
 - The increased risks of first trimester pregnancy loss and congenital malformations when taking mycophenolate during pregnancy.
 - The importance of pregnancy prevention and planning when taking mycophenolate.

II. REMS ELEMENTS

A. Elements to Assure Safe Use

1. Training must be provided to healthcare providers who prescribe mycophenolate.

- a) Training must be provided to healthcare providers that include information on the increased risks of embryofetal toxicity and congenital malformations associated with use of mycophenolate during pregnancy using the *Mycophenolate REMS Healthcare Provider Brochure*.
- b) In order to facilitate training, Mycophenolate Sponsors must:
 - i. Ensure healthcare providers can report that they have completed training via online (Mycophenolate REMS Program website), mail, email, or fax using the *Mycophenolate REMS Prescriber Training Confirmation Form*.
 - ii. Ensure a designee of a center (e.g., transplant center) can report via mail, email, or fax using the *Mycophenolate REMS Center Training Confirmation Form* that healthcare providers at the center have completed training through a centralized process administered at the center.
 - iii. Maintain a Mycophenolate REMS Call Center (1-800-617-8191) and a Mycophenolate REMS Program website that continues for the duration of the REMS.
 - iv. Ensure within 60 calendar days of the REMS modification, the Mycophenolate REMS materials listed below are available on the Mycophenolate REMS Program website and by calling the Mycophenolate REMS Call Center.
 - v. Maintain a list of all healthcare providers who have reported completing the Mycophenolate REMS training.

- vi. Monitor distribution and prescription data monthly to identify new mycophenolate prescribers who need to be trained.
- vii. Send a *Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter* within 60 calendar days of the approval of the REMS modification. The intended audience must be all healthcare providers who prescribed mycophenolate at least three times in the 12 months prior to the date of the REMS modification approval (11/13/2015). The *Mycophenolate REMS DHCP Letter* must address the increased risks of embryofetal toxicity and congenital malformations associated with use of mycophenolate during pregnancy. Mycophenolate Sponsors must make the *Mycophenolate REMS DHCP Letter* available via a link from the Mycophenolate REMS Program website for one (1) year after the approval of the REMS modification.

Send a Mycophenolate REMS Dear Healthcare Provider Letter for Centers within 60 calendar days of the approval of the REMS modification to all transplant centers.

Email must be used as the primary method to disseminate the *Mycophenolate REMS Dear Healthcare Provider Letter* and the *Mycophenolate REMS Dear Healthcare Provider Letter for Centers*. If an email is marked as unopened, a second email must be sent within 7 calendar days of the date that the first email was sent. If the second email is marked as unopened, the Mycophenolate REMS letter must be mailed in a hard copy within 30 calendar days of the date that the second email was sent. If a healthcare provider's email address is not available or the email is undeliverable, the Mycophenolate REMS letter must be mailed in hard copy within 30 calendar days of the date that the first set of emails were sent.

c) The following materials are part of the Mycophenolate REMS and are appended:

- *Mycophenolate REMS Healthcare Provider Brochure*
- *Mycophenolate REMS Patient-Prescriber Acknowledgement Form*
- *Mycophenolate REMS Prescriber Training Confirmation Form*
- *Mycophenolate REMS Center Training Confirmation Form*
- *Mycophenolate REMS Dear Healthcare Provider Letter for Centers*
- *Mycophenolate REMS Dear Healthcare Provider Letter*
- *Mycophenolate REMS Obstetrician/Gynecologist Referral Template Letter for Contraception Counseling*
- *Mycophenolate REMS Obstetrician/Gynecologist Referral Template Letter for Preconception Counseling*
- *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate*
- *Mycophenolate REMS Program Website*

2. Mycophenolate Sponsors must maintain a centralized pregnancy registry (the Mycophenolate Pregnancy Registry) for females who become pregnant and consent to participate.

The primary objectives of the Registry are to:

- Document maternal and fetal outcomes of each exposed pregnancy to further characterize the risk of mycophenolate fetal exposure.
- Determine mycophenolate exposure status for each reported pregnancy.
- Understand the circumstances that led to the fetal exposure (root cause analysis).
- Identify factors that affect the risk of adverse outcomes such as dose, timing of exposure, or maternal characteristics.

III. Timetable for Submission of Assessments

Mycophenolate NDA Sponsors must submit REMS assessments to the FDA at 6 months and 12 months from the date of initial approval of the Mycophenolate REMS (09/25/2012) and then annually, thereafter.

To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each submission will conclude no earlier than 60 calendar days before the submission date for that assessment. Mycophenolate NDA Sponsors must submit each assessment so that it will be received by the FDA on or before the due date.

Mycophenolate REMS Healthcare Provider Brochure



MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS AND CONGENITAL MALFORMATIONS

MYCOPHENOLATE REMS HEALTHCARE PROVIDERS BROCHURE

For complete safety information, please see *Prescribing Information*, including **Boxed WARNING** and *Medication Guide*, which can be found at www.MycophenolateREMS.com.



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Introducing Mycophenolate REMS

The FDA (Food and Drug Administration) requires a REMS (Risk Evaluation and Mitigation Strategy) to ensure the benefits of taking a drug outweigh the serious risks.

The Mycophenolate REMS has been required by the FDA due to postmarketing reports showing that exposure to mycophenolate during pregnancy is associated with increased risks of first trimester pregnancy loss and congenital malformations. While available data are limited, structural malformations occur in approximately 20% of live-born infants exposed in utero to mycophenolate and first trimester pregnancy loss rates are higher.*†

Mycophenolate is available by prescription as:

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

The goal of the Mycophenolate REMS is to mitigate the risk of embryofetal toxicity associated with use of mycophenolate during pregnancy by:

1. Educating healthcare providers (HCPs) on the following:
 - The increased risks of first trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy.
 - The need to counsel females of reproductive potential on the importance of pregnancy prevention and planning when taking mycophenolate.
 - The need to report pregnancies to the Mycophenolate Pregnancy Registry.
2. Informing female patients of reproductive potential who are prescribed mycophenolate about:
 - The increased risks of first trimester pregnancy loss and congenital malformations when taking mycophenolate during pregnancy.
 - The importance of pregnancy prevention and planning when taking mycophenolate.

*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.

For complete safety information, please see *Prescribing Information*, including **Boxed WARNING and *Medication Guide*, which can be found at www.MycophenolateREMS.com**



Introducing Mycophenolate REMS (cont'd)

All prescribers of mycophenolate and females of reproductive potential, whether or not they plan to get pregnant, should be aware of the risks associated with mycophenolate.

Definitions:

Females of reproductive potential include girls who have entered puberty and all women who have a uterus and have not passed through menopause.

Menopause is the permanent end of menstruation and fertility.

Menopause should be clinically confirmed by a patient's healthcare practitioner. Some commonly used diagnostic criteria include:

1. 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy)
2. Post-surgical from a bilateral oophorectomy

This brochure, the *Mycophenolate REMS Healthcare Provider Brochure*, has been designed to help you understand the components of the Mycophenolate REMS. Included are details on what you can do to help ensure the implementation of the Mycophenolate REMS so that patients understand the risks associated with exposure to mycophenolate during pregnancy.

Increased Risks of First Trimester Pregnancy Loss and Congenital Malformations

Mycophenolate can cause fetal harm when administered to a pregnant female. Exposure to mycophenolate during pregnancy is associated with an increased risk of:

- First trimester pregnancy loss
- Congenital malformations, especially:
 - external ear
 - cleft lip and palate abnormalities
- Anomalies of:
 - the distal limbs
 - heart
 - esophagus
 - kidney
 - nervous system

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

- 15 spontaneous abortions (45%)
- 18 live-born infants
 - Four of the 18 live-born infants had structural malformations (22%)

Of the 77 females exposed to systemic mycophenolate during pregnancy that were reported in postmarketing data[†] (collected between 1995 and 2007):

- 25 had spontaneous abortions
- 14 had a malformed fetus or infant
 - Six of the 14 malformed offspring had ear abnormalities

The reported malformations were similar to findings in animal reproductive toxicology studies. For comparison, background rate for congenital anomalies in the United States is about 3% and the NTPR data show a rate of 4% to 5% among babies born to organ-transplant patients using other immunosuppressive drugs. Because these postmarketing data are reported voluntarily, it is not always possible to reliably estimate the frequency of particular outcomes.

*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.

Your Role in Mycophenolate REMS

You need to complete the following steps to help ensure the implementation of Mycophenolate REMS with females of reproductive potential:

1. **Document** your Training in the Mycophenolate REMS program
2. **Educate** Females of Reproductive Potential
3. **Obtain** a Signed *Mycophenolate REMS Patient-Prescriber Acknowledgment Form* from Females of Reproductive Potential
4. **Check** Pregnancy Status
5. **Report** any Mycophenolate-Exposed Pregnancies

1. Document your Training in the Mycophenolate REMS

You should become familiar with the risks of embryofetal toxicity associated with mycophenolate and the requirements of Mycophenolate REMS.

As a prescriber of mycophenolate, you should document your training by completing a *Mycophenolate REMS Prescriber Training Confirmation Form* to document that you understand, and will comply with Mycophenolate REMS.

You can submit a prescriber training confirmation form to Mycophenolate REMS by one of several ways:

- Visit www.MycophenolateREMS.com and complete the online form
- Complete a hard copy and submit it via fax to **1-800-617-5768**
- Complete a hard copy and mail it to:
Mycophenolate REMS
200 Pinecrest Plaza
Morgantown, WV 26505-8065
- Call **1-800-617-8191**

This brochure is not a comprehensive description of the risks associated with the use of mycophenolate.

2. Educate Females of Reproductive Potential

■ Educate females about the risks of mycophenolate exposure during pregnancy.

Discuss the increased risks of first trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy with females of reproductive potential before initiating or continuing treatment

The information you share in this discussion will be reinforced by the *Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate*.

■ Provide females of reproductive potential with a *Mycophenolate REMS Overview & Your Birth Control Options* booklet.

Patients need to understand:

- 1) the increased risks of first trimester pregnancy loss and congenital malformations while using mycophenolate
- 2) their birth control options
- 3) their role in the Mycophenolate REMS program

■ Provide pregnancy planning education

- Advise patients using mycophenolate to let you know if they are considering pregnancy.
- Determine whether there are appropriate treatment options with less potential for embryofetal toxicity.
- It is important to optimize the patient's underlying medical condition(s) and nutritional status prior to conception.
- Refer patients for pre-conception counseling and high risk obstetrical care as needed and coordinate care among the patient's established providers.

■ Provide contraception counseling

Unless patients choose not to have sexual intercourse with a man at any time (abstinence), you must instruct them to always use acceptable contraception:

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

Your Role in Mycophenolate REMS (cont'd)

The following table lists the forms of contraception that are acceptable for use during treatment with mycophenolate. Guide your patients to choose from the following birth control options:

Acceptable Contraception Methods for Females of Reproductive Potential*			
Option 1 Methods to Use Alone	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 Oral contraceptive pill Transdermal patch Vaginal ring Progesterone-only Injection Implant	AND	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
	Diaphragm with spermicide Cervical cap with spermicide Contraceptive sponge	AND	Male condom Female condom

***Females of reproductive potential** include girls who have entered puberty and all women who have a uterus and have not passed through menopause.

Note: Mycophenolate reduces blood levels of the hormones in the oral contraceptive pill and could theoretically reduce its effectiveness. Therefore, an additional barrier method of contraception must be used with all hormonal methods.



EMERGENCY CONTRACEPTION

- Patients should also be counseled on the availability of emergency contraception in the event they have intercourse without acceptable contraception or their contraceptive methods fail.
- Patients 17 years and older can purchase emergency contraception over the counter.

3. Obtain a signed *Mycophenolate REMS Patient-Prescriber Acknowledgment Form*

- **Patients and prescribers should sign the patient-prescriber acknowledgment form.**

By signing this form, patients agree that they will comply with Mycophenolate REMS program. For patients who are minors, a legal guardian needs to sign in addition to the patient.

You too, as the prescriber, should sign the form and give a signed copy to the patient.

Retain the original signed copy for your records.

Your Role in Mycophenolate REMS (cont'd)

4. Check Pregnancy Status

You must determine if females of reproductive potential are pregnant:

- One pregnancy test with a sensitivity of at least 25 mIU/mL should be done immediately before starting mycophenolate
- Another pregnancy test with the same sensitivity should be done 8 to 10 days later
- Repeat pregnancy tests should be performed at routine follow-up visits
- Results of all pregnancy tests should be discussed with the patient
 - In the event of a positive pregnancy test, patients should continue to take mycophenolate until a discussion can take place on the risks and benefits of mycophenolate treatment with the patient.
 - The patient should be apprised of the potential hazard to the fetus.
 - In certain situations, you and the patient may decide that the maternal benefits outweigh the risks to the fetus.

5. Report any pregnancies to the Mycophenolate Pregnancy Registry

The Mycophenolate Pregnancy Registry has been established to evaluate mycophenolate-exposed pregnancies and their outcomes. These data will provide an opportunity to learn more about mycophenolate exposure in utero.

Instruct patients to tell you if they get pregnant during treatment with mycophenolate or within 6 weeks following discontinuation of treatment.

If you learn that a patient is pregnant:

- Report the pregnancy to the Mycophenolate Pregnancy
 - By phone: **1-800-617-8191**
 - Online:
www.MycophenolatePregnancyRegistry.com; or
 - By mail:
Mycophenolate Pregnancy Registry
200 Pinecrest Plaza
Morgantown, WV 26505-8065

Reporting a Pregnancy

Patients should be informed that you will report any pregnancies of which you become aware to the Mycophenolate Pregnancy Registry. Provision of patient contact and medical information to the Mycophenolate Pregnancy Registry is covered by an HIPAA waiver.

- Encourage the patient to participate in the Mycophenolate Pregnancy Registry

Mycophenolate REMS Resources

These resources have been developed to help ensure that you and your patients understand the risks associated with exposure to mycophenolate during pregnancy and to comply with the requirements of the Mycophenolate REMS.

These resources, some of which have been described previously, are available either in the

- **Mycophenolate REMS Web Site:**
www.MycophenolateREMS.com

The website provides information about Mycophenolate REMS, including the option to order or download resource materials. All REMS materials for HCPs and patients are available on this website. Prescribers can document their training in the Mycophenolate REMS on this website.

- **Mycophenolate REMS Healthcare Provider Brochure** (this brochure)

- **Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate**

This brochure helps patients understand the increased risks of first trimester pregnancy loss and birth defects with mycophenolate, provides an overview of acceptable forms of contraception, and the Mycophenolate REMS program. You should provide your patient with this brochure.

- **Mycophenolate REMS Patient-Prescriber Acknowledgment Form**

- **Mycophenolate REMS Prescriber Training Confirmation Form**

Prescribers document training in Mycophenolate REMS by completing this form

- **Mycophenolate REMS Center Training Confirmation Form**

Centers document training in Mycophenolate REMS by completing this form

- **Mycophenolate REMS Obstetrician/Gynecologist Referral Template Letters**

These customizable letters available online at Letters can be used by prescribers of mycophenolate to help establish a working relationship with an OB/GYN for patient counseling. There are 2 letter templates—one for contraception counseling and one for pregnancy planning education—that can be customized for your practice and patient before sending to an OB/GYN

- **Medication Guide**

There is a separate Medication Guide for each mycophenolate formulation

- **Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients**

This document answers some common questions about the Mycophenolate Pregnancy Registry in patient-friendly language

Mycophenolate REMS Resources (cont'd)

■ Mycophenolate Pregnancy Registry

The Mycophenolate Pregnancy Registry evaluates mycophenolate-exposed pregnancies and their outcomes. You can contact the Mycophenolate Pregnancy Registry by calling **1-800-617-8191** or visiting www.MycophenolatePregnancyRegistry.com

For more information about Mycophenolate REMS and for all resource materials

- Visit www.MycophenolateREMS.com
- Call **1-800-617-8191**

Additional Resources

FOR MORE INFORMATION ABOUT CONTRACEPTION*

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

FOR MORE INFORMATION ABOUT BIRTH DEFECTS*

- Centers for Disease Control and Prevention: www.cdc.gov

*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 medical advice to your patients.



MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS AND CONGENITAL MALFORMATIONS

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BHCP 11/11

Mycophenolate REMS Prescriber Training Confirmation Form

PRESCRIBER TRAINING CONFIRMATION FORM

The FDA determined that a REMS (Risk Evaluation and Mitigation Strategy) is necessary to ensure that the benefits of mycophenolate outweigh the increased risks of first trimester pregnancy loss and congenital malformations associated with mycophenolate use during pregnancy.

Mycophenolate is available by prescription as

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

As a prescriber of mycophenolate to females of reproductive potential,* I understand that I need to complete and return the training confirmation form to document my training in the Mycophenolate REMS program.

*A female of reproductive potential includes girls who have entered puberty and all females who have a uterus and have not passed through menopause.

I agree to do the following:

1. Read and understand the *Prescribing Information* for mycophenolate and the *Mycophenolate REMS Healthcare Provider Brochure*.
2. Understand the increased risks of first trimester pregnancy loss and congenital malformations associated with mycophenolate.
3. Educate females of reproductive potential on the risks associated with exposure to mycophenolate during pregnancy.
4. Provide the *Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate* to females of reproductive potential.
5. Provide contraception counseling to patients directly or by partnering with an OB/GYN.
6. Only prescribe mycophenolate to a pregnant patient if the benefits of initiating or continuing mycophenolate treatment outweigh the risk of fetal harm.
7. Discuss alternative treatments to mycophenolate with females of reproductive potential who are pregnant or considering pregnancy.
8. Follow the pregnancy testing recommendations as outlined in the *Prescribing Information* for mycophenolate and the *Mycophenolate REMS Healthcare Provider Brochure*.
9. Report to the Mycophenolate Pregnancy Registry any pregnancies that occur during mycophenolate treatment or within 6 weeks following discontinuation of treatment. Encourage pregnant patients to participate in the Mycophenolate Pregnancy Registry.
10. Obtain a signed *Mycophenolate REMS Patient-Prescriber Acknowledgment Form* from each female of reproductive potential.

I understand that I may be contacted in the future for items pertaining to the administration of Mycophenolate REMS.

Please Print:

Prescriber First Name: _____ Prescriber Last Name: _____

Prescriber Degree: (Circle one) MD DO NP PA

Specialty Code (Select one from the back of this form): _____ National Provider Identifier: _____

Prescriber E-mail Address: _____

Facility: _____

Address 1: _____

Address 2: _____

City: _____ State: _____ ZIP: _____

Telephone: _____ Fax: _____

Prescriber Signature: _____ Date: _____

Healthcare Provider acting on behalf of the prescriber: _____

Degree: (Circle one) RN LPN NP PA RPH PharmD CSW

For complete safety information, please see *Prescribing Information*, including Boxed WARNING and Medication Guide, which can be found at www.MycophenolateREMS.com.

You can submit a *Mycophenolate REMS Prescriber Training Confirmation Form* by visiting www.MycophenolateREMS.com and completing the online form.

If you prefer, you can complete the paper form and return it via fax to 1-800-617-5768 or mail it to:

Mycophenolate REMS
[Current Vendor Address]

You can also call 1-800-617-8191 to complete a prescriber training confirmation form.

For more information about Mycophenolate REMS, visit www.MycophenolateREMS.com or call 1-800-617-8191.

Specialty	Specialty Code
Allergy and Immunology _____	1
Cardiology _____	2
Dermatology _____	3
Family Practitioner _____	4
Gastroenterology _____	5
Hepatology _____	6
Internal Medicine _____	7
Nephrology _____	8
Neurology _____	9
OB/GYN _____	10
Pediatric _____	11
Rheumatology _____	12
Surgery _____	13
Transplant _____	14
Other _____	15

Mycophenolate REMS Center Training Confirmation Form

CENTER TRAINING CONFIRMATION FORM

The FDA determined that a REMS (Risk Evaluation and Mitigation Strategy) is necessary to ensure that the benefits of mycophenolate outweigh the increased risks of first trimester pregnancy loss and congenital malformations associated with mycophenolate use during pregnancy.

Mycophenolate is available by prescription as:

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

On behalf of prescribers of mycophenolate to females of reproductive potential,* _____ will complete and return this training form to document training in Mycophenolate REMS. *Center Name*

*A female of reproductive potential includes girls who have entered puberty and all women who have a uterus and have not passed through menopause.

We agree to do the following:

1. Read and understand the *Prescribing Information* for mycophenolate and the *Mycophenolate REMS Healthcare Provider Brochure*.
2. Understand the increased risks of first trimester pregnancy loss and congenital malformations associated with mycophenolate.
3. Educate females of reproductive potential on the risks associated with exposure to mycophenolate during pregnancy.
4. Provide a *Mycophenolate REMS Patient Brochure: What You Need to Know about Mycophenolate* to females of reproductive potential.
5. Provide contraception counseling to patients directly or by partnering with an OB/GYN.
6. Only prescribe mycophenolate to a pregnant patient if the benefits of initiating or continuing treatment outweigh the risk of fetal harm.
7. Discuss alternative treatments to mycophenolate with females of reproductive potential who are pregnant or considering pregnancy.
8. Follow the pregnancy testing recommendations as outlined in the full *Prescribing Information* for mycophenolate and the *Mycophenolate REMS Healthcare Provider Brochure*.
9. Report to the Mycophenolate Pregnancy Registry any pregnancies that occur during mycophenolate treatment or within 6 weeks following discontinuation of treatment. Encourage pregnant patients to participate in the Mycophenolate Pregnancy Registry.
10. Obtain a signed *Mycophenolate REMS Patient-Prescriber Acknowledgment Form* from each female of reproductive potential.
11. Describe how your center plans to implement the program requirements (please explain/outline process below):

I understand that I may be contacted in the future for items pertaining to the administration of Mycophenolate REMS.

(Please fill out form on next page)



CENTER TRAINING CONFIRMATION FORM CENTER INFORMATION

(PLEASE PRINT)

Center: _____

Center Type (disease or specialty)*: _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Fax: _____

Contact Person: _____ E-mail: _____

TRAINED PRESCRIBERS

Please complete fields below:

Prescriber Name (Printed)	Signature of Prescriber	Date	Degree (MD, DO, NP, PA)	Specialty Code(s)*	E-mail	National Provider Identifier

*A list of codes can be found on page 4.

■ Healthcare providers acting on behalf of the prescriber should fill out the form on the next page.

You can submit a completed *Mycophenolate REMS Center Training Confirmation Form* via fax to 1-800-617-5768 or mail it to:

Mycophenolate REMS
 [Current Vendor Address]

For more information about Mycophenolate REMS, visit www.MycophenolateREMS.com or call 1-800-617-8191.

Prescriber Specialty	Prescriber Specialty Code
Allergy and Immunology	1
Cardiology	2
Dermatology	3
Family Practitioner	4
Gastroenterology	5
Hepatology	6
Internal Medicine	7
Nephrology	8
Neurology	9
OB/GYN	10
Pediatric	11
Rheumatology	12
Surgery	13
Transplant	14
Other	15

Center Type	Center Type Code
Allergy and Immunology	1
Cardiology	2
Dermatology	3
Dermatology Surgery	4
Dermatopathology	5
Gastroenterology	6
General Surgery	7
Hepatology	8
Immunology	9
Maternal Fetal Medicine	10
Nephrology	11
Neurologic Surgery	12
Neurology	13
Neuropathology	14
OB/GYN	15
Rheumatology	16
Thoracic Surgery	17
Transplantation Surgery	18

Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter



Important Updates from the Mycophenolate REMS*

Dear Healthcare Provider:

If you prescribe mycophenolate containing products, you should be aware that there are **increased risks of first trimester pregnancy loss and congenital malformations** associated with exposure to mycophenolate during pregnancy. However, a recent survey of female patients taking mycophenolate during reproductive age indicates that **many patients do NOT understand these risks**.

Have the important conversation with your patients:

With your involvement, we can improve patient understanding and reduce the number of unplanned pregnancies to women taking mycophenolate.

Discuss the following with your female patients of reproductive potential:

- The **increased risks** of first trimester pregnancy loss and congenital malformations while taking mycophenolate.
- **Pregnancy tests** should to be conducted before and during mycophenolate treatment.
- **Birth control** needs to be used while taking mycophenolate, and for 6 weeks after stopping treatment, to avoid pregnancy.
- **Pregnancy planning** needs to be discussed with a healthcare provider if a patient wishes to become pregnant during mycophenolate treatment.
- **All pregnancies** need to be **reported** to the mycophenolate pregnancy registry, 1-800-617-8191, or online at www.mycophenolatepregnancyregistry.com, or www.MycophenolateREMS.com.

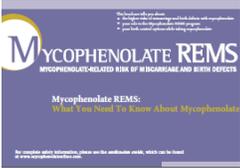
Training tools are available for patients:

- **Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate.** This brochure discusses the risks of pregnancy loss and birth defects, birth control options and information on the mycophenolate REMS program.
- **Mycophenolate REMS Prescriber-Patient Acknowledgement Form.** This form can be used to discuss the risks associated with use of mycophenolate. Prescribers and patients should sign this form.

Materials are available at www.MycophenolateREMS.com or by calling **1-800-617-8191**. A list of available tools is found on the back of this letter.

Thank you for your commitment to helping female patients of reproductive potential understand the risks and benefits associated with mycophenolate treatment.

Sincerely,
Mycophenolate REMS Team

Training Tools		Web Link Or How To Order
	<p>Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientResourceKit.pdf</p>
	<p>Mycophenolate REMS Patient-Prescriber Acknowledgement Form</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientAgreement.pdf</p>
	<p>Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientRegistryFAQ.pdf</p>
	<p>Mycophenolate REMS Healthcare Provider Brochure</p>	<p>https://www.mycophenolate.rems.com/Docs/PrescriberProgramBrochure.pdf</p>
	<p>Medication Guides</p>	<p>https://www.mycophenolate.rems.com/SafetyInformation.aspx</p>

Mycophenolate REMS
Dear Center Director Letter



Important Updates from the Mycophenolate REMS*

Dear Center Director:

If you prescribe mycophenolate containing products, you should be aware that there are **increased risks of first trimester pregnancy loss and congenital malformations** associated with exposure to mycophenolate during pregnancy. However, a recent survey of female patients taking mycophenolate during reproductive age indicates that **many patients do NOT understand these risks.**

Have the important conversation with your patients:

With your involvement, we can improve patient understanding and reduce the number of unplanned pregnancies to women taking mycophenolate.

Healthcare providers should discuss the following with female patients of reproductive potential:

- The **increased risks** of first trimester pregnancy loss and congenital malformations while taking mycophenolate.
- **Pregnancy tests** should to be conducted before and during mycophenolate treatment.
- **Birth control** needs to be used while taking mycophenolate, and for 6 weeks after stopping mycophenolate treatment, to avoid pregnancy.
- **Pregnancy planning** needs to be discussed with a healthcare provider if a patient wishes to become pregnant during mycophenolate treatment.
- **All pregnancies** need to be **reported** to the mycophenolate pregnancy registry, 1-800-617-8191, or online at www.mycophenolatepregnancyregistry.com, or www.MycophenolateREMS.com.

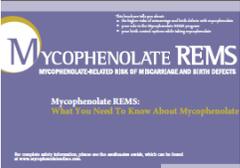
Training tools are available for patients:

- **Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate.** This brochure discusses the risks of pregnancy loss and birth defects, birth control options and the mycophenolate REMS program.
- **Mycophenolate REMS Prescriber-Patient Acknowledgement Form.** This form can be used to discuss the risks associated with use of mycophenolate. Prescribers and patients should sign this form.

For more information about Mycophenolate REMS, including all program materials and instructions on how to enroll, please visit www.MycophenolateREMS.com or call **1-800-617-8191**.

Thank you for your commitment to helping females patients of reproductive potential understand the risks and benefits associated with mycophenolate treatment.

Sincerely,
Mycophenolate REMS Team

Training Tools	Web Link Or How To Order	
	<p>Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientResourceKit.pdf</p>
	<p>Mycophenolate REMS Patient-Prescriber Acknowledgement Form</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientAgreement.pdf</p>
	<p>Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientRegistryFAQ.pdf</p>
	<p>Mycophenolate REMS Healthcare Provider Brochure</p>	<p>https://www.mycophenolate.rems.com/Docs/PrescriberProgramBrochure.pdf</p>
	<p>Medication Guides</p>	<p>https://www.mycophenolate.rems.com/SafetyInformation.aspx</p>

Mycophenolate REMS OB/GYN Contraception Counseling Letter

((Date))

((Recipient's Name))

((Recipient's Address 1))

((Recipient's Address 2))

((City, State, ZIP))

In reference to: My patient ((Patient's Name))

Reason for the referral: Contraception counseling

Dear Dr ((Recipient's Last Name)):

I am writing to you in reference to the above-named patient who is under my care for ((diagnosis)) and ((insert drug information such as drug name, when patient will begin taking the drug, if treatment has already begun, etc)). This medication contains mycophenolate, which is associated with an increased risk of first trimester pregnancy loss and congenital malformations. It is important that this patient receive contraception counseling about methods that are acceptable for use while taking mycophenolate.

Prescribers of mycophenolate participate in the FDA-required Mycophenolate REMS (Risk Evaluation and Mitigation Strategy) to ensure that the benefits of mycophenolate outweigh the risks.

The following table lists the forms of contraception that are acceptable for use during treatment with mycophenolate.

Acceptable Contraception Methods for Females of Reproductive Potential

Guide your patients to choose from the following birth control options:

Option 1	<ul style="list-style-type: none"> ■ Intrauterine devices (IUDs) ■ Tubal sterilization ■ Patient's partner had a vasectomy
Methods to Use Alone	

OR

Option 2	Hormone Methods choose 1		Barrier Methods choose 1
Choose One Hormone Method AND One Barrier Method	Estrogen and Progesterone	<i>AND</i>	<ul style="list-style-type: none"> ■ Diaphragm with spermicide ■ Cervical cap with spermicide ■ Contraceptive sponge ■ Male condom ■ Female condom
	<ul style="list-style-type: none"> ■ Oral contraceptive pill ■ Transdermal patch ■ Vaginal ring Progesterone-only <ul style="list-style-type: none"> ■ Injection ■ Implant 		

OR

Option 3	Barrier Methods choose 1		Barrier Methods choose 1
Choose One Barrier Method From Each Column (must choose two methods)	<ul style="list-style-type: none"> ■ Diaphragm with spermicide ■ Cervical cap with spermicide ■ Contraceptive sponge 	<i>AND</i>	<ul style="list-style-type: none"> ■ Male condom ■ Female condom

Patients should be aware that mycophenolate reduces blood levels of the hormones in the oral contraceptive pill and could reduce its effectiveness. An additional barrier method must be used with any hormonal contraceptives.

Patients should also be counseled on the availability of emergency contraception.

Unless patients choose to remain abstinent, they should be instructed to use acceptable birth control during the entire treatment with mycophenolate and for 6 weeks after they stop taking mycophenolate.

You can find more information about Mycophenolate REMS, including the roles and responsibilities of patients and prescribers of mycophenolate, at www.MycophenolateREMS.com. The site provides educational materials, as well as access to *Prescribing Information* and *Medication Guides* for mycophenolate-containing products.

Please call me at ((Signatory's phone)) at your earliest convenience. Thank you for your cooperation.

Sincerely,

((Signatory's Name))

((Signatory's Practice))

Mycophenolate REMS OB/GYN Preconception Counseling Letter

((Date))

((Recipient's Name))

((Recipient's Address 1))

((Recipient's Address 2))

((City, State, ZIP))

In reference to: My patient ((Patient's Name))

Reason for referral: Pre-conception counseling

Dear Dr ((Recipient's Last Name)):

I am writing to you in reference to the above-named patient who is under my care for ((diagnosis)) and ((insert drug information such as drug name, when patient will begin taking the drug, if treatment has already begun, etc)). This medication contains mycophenolate, and the patient is considering a pregnancy. Because exposure to mycophenolate during pregnancy is associated with increased risks of first trimester pregnancy loss and congenital malformations, it is important that this patient receive pregnancy planning education. There are three components to pregnancy planning which include the following:

1. Pre-conception counseling
2. Determining whether there are appropriate treatment options with less potential for embryofetal toxicity
3. Optimizing the patient's underlying medical conditions prior to conception

I would like you to provide pre-conception counseling in order to optimize the patient's future pregnancy outcome. Although a decision regarding treatment options with less potential for embryofetal toxicity may not have been made at the present time, these discussions will be done by my practice.

Prescribers of mycophenolate participate in the FDA-required Mycophenolate REMS (Risk Evaluation and Mitigation Strategy) to ensure that the benefits of mycophenolate outweigh the risks.

You can find more information about Mycophenolate REMS, including the roles and responsibilities of patients and prescribers of mycophenolate, at www.MycophenolateREMS.com. The site provides educational materials, as well as access to *Prescribing Information* and *Medication Guides* for mycophenolate-containing products.

I look forward to working with you to ensure that this patient receives appropriate pregnancy planning education. ((Insert any further details specific to this patient that the OB/GYN should know.))

Please call me at ((Signatory's phone)) at your earliest convenience. Thank you for your cooperation.

Sincerely,

((Signatory's Name))

((Signatory's Practice))

Mycophenolate REMS Patient-Prescriber Acknowledgement Form

PATIENT-PRESCRIBER ACKNOWLEDGMENT FORM

For the patient:

Please read each item below. Discuss them with your doctor. Do not sign this form until you are sure you understand it.

By signing on the next page, I am stating that

1. My doctor gave me the *Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate*.
2. I know the risks to an unborn baby if I take mycophenolate while I am pregnant. I talked with my doctor about these risks. I understand that if I get pregnant while taking mycophenolate or within 6 weeks after I stop, there is
 - A higher risk of losing the pregnancy (miscarriage) in the first 3 months
 - A higher risk that the baby may have birth defects including:
 - Defects of the ears
 - Cleft lip or cleft palate
 - Defects of the arms, legs, heart, esophagus, kidney and nervous system
3. I know I will have pregnancy tests before I start and during my mycophenolate treatment
4. My doctor talked with me about acceptable forms of birth control.
5. Unless I choose not to have sexual intercourse with a man at any time (abstinence), I will always use acceptable birth control
 - During my entire treatment with mycophenolate
 - For 6 weeks after I stop taking mycophenolate

Information about your birth control options is provided in the *Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate* If I am thinking about having a baby during my treatment, I will talk with my doctor right away.

6. I will tell my doctor right away if I get pregnant during my treatment or within 6 weeks after I stop.
7. I know that if I become pregnant I should report it to the Mycophenolate Pregnancy Registry.

These medicines contain mycophenolate:

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

(Please fill out form on next page)

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

PATIENT-PRESCRIBER ACKNOWLEDGMENT FORM

Patient Name (please print): _____

Patient Signature: _____ Date: _____

Parent/Guardian Name (if patient under age 18; please print): _____

Parent/Guardian Signature: _____ Date: _____

For the prescriber (or healthcare provider acting on behalf of the prescriber):

I have fully explained to my patient (and her parent or guardian if the patient is under age 18) the nature and purpose of treatment with mycophenolate and the risks to females of reproductive potential as described on the previous page. I have asked the patient (and her parent or guardian) if she has any questions regarding her treatment and have answered those questions to the best of my ability.

Prescriber's/Other Healthcare Provider's Name (please print): _____

Degree: (Circle one) MD DO NP PA

Prescriber's/Other Healthcare Provider's Signature: _____

Date: _____

PLEASE RETAIN THE ORIGINAL SIGNED DOCUMENT AND PROVIDE A SIGNED COPY TO THE PATIENT.

For more information about Mycophenolate REMS and to request resource materials, please visit www.MycophenolateREMS.com or call **1-800-617-8191**.

Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate



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.



**OVERVIEW
FOR PATIENTS**

MYCOPHENOLATE REMS

MYCOPHENOLATE-RELATED RISK OF MISCARRIAGE AND BIRTH DEFECTS

Table of Contents

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Your Birth Control Options.....	7
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Welcome to Mycophenolate REMS

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

Increased Risks of Miscarriage and Birth Defects with Mycophenolate Use

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 to learn about all of the risks of taking mycophenolate.

What You Need to Know about Pregnancy Prevention

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

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

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			
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.

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**
- Upon enrollment in the registry, patients will be asked to provide informed consent and medical release.

Important Resources

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
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

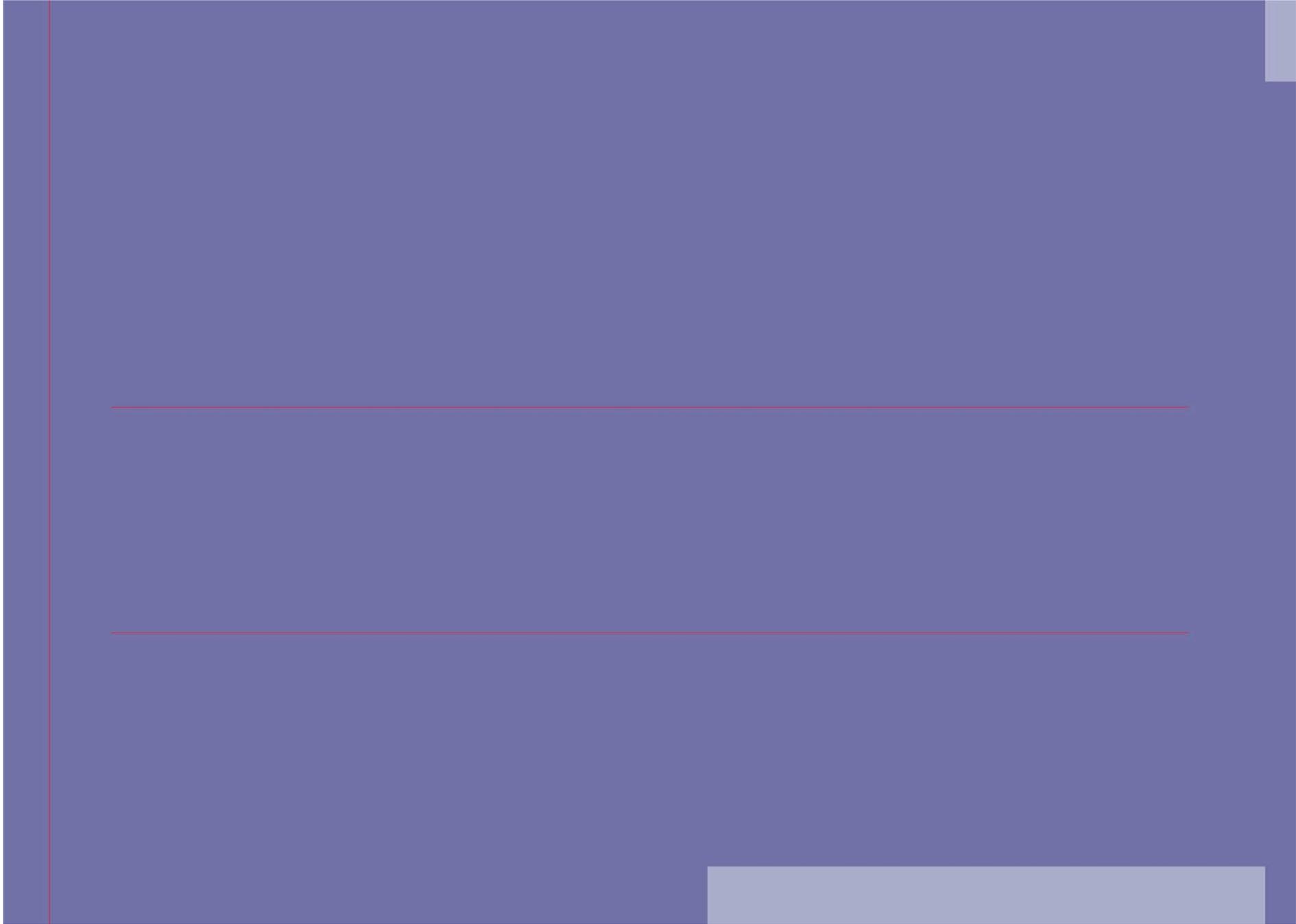
For emergency birth control*

- Call your doctor or pharmacy

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
- 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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Mycophenolate REMS Website Screenshots



[Prescriber Overview](#)

[Patient Overview](#)

[Other Healthcare Professionals Overview](#)

[REMS Materials](#)

[Report a Pregnancy](#)

[Additional Resources](#)

[FAQs](#)

WELCOME TO THE MYCOPHENOLATE REMS (Risk Evaluation and Mitigation Strategy)

What is the Mycophenolate REMS?

The Mycophenolate REMS is a program to tell doctors, nurses, pharmacists and patients about the risks of taking mycophenolate during pregnancy. It was required by the Food and Drug Administration (FDA).

What are the risks of mycophenolate during pregnancy?

- Higher risk of miscarriage in the first 3 months.
- Higher risk that the baby will have birth defects.

Who should be informed about the Mycophenolate REMS?

Report a Pregnancy To Report a Pregnancy, click here	Prescribers For Prescriber Overview, click here	Other Healthcare Professionals For Other Healthcare Professionals, click here	Patients For Patient Overview, click here
---	--	--	--

What is the goal of the Mycophenolate REMS? The goal of the Mycophenolate REMS is to mitigate the risk of embryofetal toxicity associated with the use of mycophenolate during pregnancy by:

1. Educating healthcare providers on the following:
 - The increased risks of first trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy.
 - The need to counsel females of reproductive potential on the importance of pregnancy prevention and planning when taking mycophenolate.

The need to report pregnancies to the Mycophenolate Pregnancy Registry.
2. Informing females of reproductive potential who are prescribed mycophenolate about:
 - The increased risks of first trimester pregnancy loss and congenital malformations when taking mycophenolate during pregnancy.
 - The importance of pregnancy prevention and planning when taking mycophenolate.

What medications contain mycophenolate?

Mycophenolate Mofetil

CellCept® by Genentech USA, Inc.

[Generic formulations by >>](#)

Mycophenolic Acid

Myfortic® by Novartis Pharmaceuticals Corporation.

[Generic formulations by >>](#)

*Females of reproductive potential include girls who have entered puberty and all women who have a uterus and have not passed through menopause.



Prescriber Overview Page

Accessed from Main menu links or Prescribers button on Home page

INFORMATION FOR PRESCRIBERS

What is my role in the Mycophenolate REMS? *Click step to expand details.*

- + **Step 1 - Document your training in the Mycophenolate REMS**
- + **Step 2 - Educate Females of Reproductive Potential**
- + **Step 3 - Obtain a signed Patient-Prescriber Acknowledgment form**
- + **Step 4 - Check Pregnancy Status**
- + **Step 5 - Report any pregnancies to the Mycophenolate Pregnancy Registry**

Do prescribers have to be trained in the Mycophenolate REMS in order to prescribe mycophenolate-containing products?

Healthcare professionals are not required to complete the *Mycophenolate REMS Prescriber Training Confirmation Form* in order to prescribe mycophenolate-containing medicines. However, healthcare professionals who prescribe mycophenolate-containing medicines will be contacted by the Mycophenolate REMS Program and encouraged to review the program materials and complete a *Mycophenolate REMS Prescriber Training Confirmation Form* (online or paper).

Report a Pregnancy

To report a pregnancy, [click here](#).

Prescriber Training

To view the *Mycophenolate REMS Healthcare Providers Brochure*, [click here](#).

Program Materials

Download or Order materials, [click here](#).

Document Your Training

To Document Your Training, [click here](#).

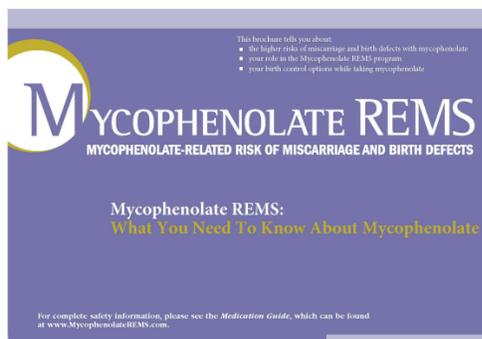
Program Resources and Educational Materials

The Mycophenolate REMS provides the resources and educational materials you and your patients need to understand your roles and responsibilities in the program.

There are three ways to obtain program materials:

1. **ONLINE** – If you are trained in the Mycophenolate REMS you can order the materials online. [To Order Online, click here](#)
2. **BY PHONE** – If you are trained in the Mycophenolate REMS you can order materials by calling the Mycophenolate REMS call center at 1-800-617-8191.
3. **VIEW, PRINT, OR SAVE ON YOUR COMPUTER** – You can view, print, or save the materials to your computer. Select items from the list below.

Your Program Materials:



Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

- For prescribers to give to female patients of reproductive potential
- Contains the tools and materials to help patients understand the components of the Mycophenolate REMS
- Includes:
 1. [Mycophenolate REMS Patient-Prescriber Acknowledgment Form](#)

[View to Print or Save](#) | [Order](#)



Mycophenolate REMS Patient-Prescriber Acknowledgment Form

- For prescribers to give to female patients of reproductive potential
- Female patients of reproductive potential must sign this to acknowledge that they will comply with program requirements
- The *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate*; also contains a *Mycophenolate REMS Patient-Prescriber Acknowledgment Form*

[View to Print or Save](#) | [Order](#)



Mycophenolate REMS Healthcare Providers Brochure

- For prescribers
- Contains information on the risks associated with exposure to mycophenolate during pregnancy, the components of the Mycophenolate REMS, and what you can do to help ensure the successful implementation of the program.

[View to Print or Save](#) | [Order](#)



Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

[View to Print or Save](#) | [Order](#)



Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter for Centers

- For healthcare centers
- Contains important information about the Mycophenolate REMS for healthcare centers

[View to Print or Save](#) | [Order](#)



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

[View to Print or Save](#) | [Order](#)



Mycophenolate REMS Prescriber Training Confirmation Form

- For prescribers
- This form can be used to document training in the Mycophenolate REMS. The form can be filled out and mailed or faxed to document your training.

[View to Print or Save](#) | [Order](#)



Mycophenolate REMS OBGYN Referral Letter for Contraceptive Counseling

[View to Print or Save](#)



Mycophenolate REMS OBGYN Referral Letter for Pre-conception Counseling

[View to Print or Save](#)



CellCept Medication Guide

[View to Print or Save](#)

Generic Mycophenolate Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

[View to Print or Save](#)

Generic Mycophenolic Acid Medication Guide

[View to Print or Save](#)

The Mycophenolate REMS sponsors attest that this page will only include Medication Guides from the list of approved application numbers and sponsors on the FDA approved REMS website.



INFORMATION FOR PRESCRIBERS

What is my role in the Mycophenolate REMS? [Click step to expand details.](#)

Step 1 - Document your training in the Mycophenolate REMS

You should become familiar with the risks of embryofetal toxicity associated with mycophenolate and the requirements of Mycophenolate REMS:

- First-trimester pregnancy loss
- Congenital malformations, especially
 - external ear
 - cleft lip and palate abnormalities
- Anomalies of
 - the distal limbs
 - heart
 - esophagus
 - kidney
 - and nervous system

As a prescriber of mycophenolate, you should document your training in the Mycophenolate REMS by completing a Mycophenolate REMS Prescriber Training Confirmation Form to document that you understand, and will comply with Mycophenolate REMS.

You can submit a Mycophenolate REMS Prescriber Training Confirmation Form to Mycophenolate REMS by one of several ways:

- Visit www.MycophenolateREMS.com and complete the online form
- Complete a hard copy and submit it via fax to 1-800-617-5768
- Complete a hard copy and mail it to:

Mycophenolate REMS
200 Pinecrest Plaza
Morgantown, WV 26505-8065

- Call 1-800-617-8191

Step 2 - Educate Females of Reproductive Potential

Step 3 - Obtain a signed Patient-Prescriber Acknowledgment form

Step 4 - Check Pregnancy Status

Step 5 - Report any pregnancies to the Mycophenolate Pregnancy Registry

Report a Pregnancy

To report a pregnancy, [click here.](#)

Prescriber Training

To view the Mycophenolate REMS Healthcare Providers Brochure, [click here.](#)

Program Materials

Download or Order materials, [click here.](#)

Document Your Training

To Document Your Training, [click here.](#)

Do prescribers have to be trained in the Mycophenolate REMS in order to prescribe mycophenolate-containing products?

Healthcare professionals are not required to complete the *Mycophenolate REMS Prescriber Training Confirmation Form* in order to prescribe mycophenolate-containing medicines. However, healthcare professionals who prescribe mycophenolate-containing medicines will be contacted by the Mycophenolate REMS Program and encouraged to review the program materials and complete a *Mycophenolate REMS Prescriber Training Confirmation Form* (online or paper).



INFORMATION FOR PRESCRIBERS

What is my role in the Mycophenolate REMS? *Click step to expand details.*

+ Step 1 - Document your training in the Mycophenolate REMS

- Step 2 - Educate Females of Reproductive Potential

- **Educate females about the risks of mycophenolate exposure during pregnancy.** Discuss the increased risks of first trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy with females of reproductive potential before initiating treatment.

The information you share in this discussion will be reinforced by the Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate.

- **Provide females of reproductive potential with a *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate.***

Patients need to understand:

- 1) the increased risks of first trimester pregnancy loss and congenital malformations while using mycophenolate
- 2) their birth control options
- 3) their role in the Mycophenolate REMS program

- **Provide pregnancy planning education.**

Advise patients using mycophenolate to let you know if they are considering pregnancy. For a patient considering pregnancy.

Determine whether there are appropriate treatment options with less potential for embryofetal toxicity.

It is important to optimize the patient’s underlying medical condition(s) and nutritional status prior to conception.

Refer patients for pre-conceptual counseling and high risk obstetrical care as needed and coordinate care among the patient’s established providers.

- **Provide contraception counseling.**

Unless patients choose not to have sexual intercourse with a man at any time (abstinence), you must instruct them to always use acceptable contraception.

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

The following table lists the forms of contraception that are acceptable for use during treatment with mycophenolate. Guide your patients to choose from the following birth control options:

[Print](#)

Report a Pregnancy
 To report a pregnancy, [click here.](#)

Prescriber Training
 To view the Mycophenolate REMS Healthcare Providers Brochure, [click here.](#)

Program Materials
 Download or Order materials, [click here.](#)

Document Your Training
 To Document Your Training, [click here.](#)

Acceptable Contraception Methods for Females of Reproductive Potential*

Option 1 Methods to Use Alone	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 Oral contraceptive pill Transdermal patch Vaginal ring	AND	Diaphragm with spermicide Cervical cap with spermicide Contraceptive sponge Male condom Female condom
	Progesterone-only Injection Implant		
OR			
Option 3 Choose One Barrier Method from each column (must choose two methods)	Barrier Methods choose 1		Barrier Methods choose 1
	Diaphragm with spermicide Cervical cap with spermicide Contraceptive sponge	AND	Male condom Female condom

* Females of reproductive potential includes girls who have entered puberty and all women who have a uterus and have not passed through menopause.

Note: Mycophenolate reduces blood levels of the hormones in the oral contraceptive pill and could theoretically reduce its effectiveness. Therefore, an additional barrier method of contraception must be used with all hormonal methods.

EMERGENCY CONTRACEPTION

- Patients should also be counseled on the availability of emergency contraception in the event they have intercourse without acceptable contraception or their contraceptive method fails.

- Patients 17 years and older can purchase emergency contraception over the counter.

+ Step 3 - Obtain a signed Patient-Prescriber Acknowledgment form

+ Step 4 - Check Pregnancy Status

+ Step 5 - Report any pregnancies to the Mycophenolate Pregnancy Registry

Do prescribers have to be trained in the Mycophenolate REMS in order to prescribe mycophenolate-containing products?

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INFORMATION FOR PRESCRIBERS

What is my role in the Mycophenolate REMS? *Click step to expand details.*

+ **Step 1 - Document your training in the Mycophenolate REMS**

+ **Step 2 - Educate Females of Reproductive Potential**

- **Step 3 - Obtain a signed Patient-Prescriber Acknowledgment form**

- Patients and prescribers should sign the *Patient-Prescriber Acknowledgment* form.

By signing this form, patients agree that they will comply with the Mycophenolate REMS program. For patients who are minors, a legal guardian should sign in addition to the patient.

You too, as the prescriber, should sign the form and give a copy to the patient.

Retain the original copy for your records.

+ **Step 4 - Check Pregnancy Status**

+ **Step 5 - Report any pregnancies to the Mycophenolate Pregnancy Registry**

 **Report a Pregnancy**

To report a pregnancy, [click here](#).

 **Prescriber Training**

To view the Mycophenolate REMS Healthcare Providers Brochure, [click here](#).

 **Program Materials**

Download or Order materials, [click here](#).

 **Document Your Training**

To Document Your Training, [click here](#).

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INFORMATION FOR PRESCRIBERS

What is my role in the Mycophenolate REMS? [Click step to expand details.](#)

- + Step 1 - Document your training in the Mycophenolate REMS**
- + Step 2 - Educate Females of Reproductive Potential**
- + Step 3 - Obtain a signed Patient-Prescriber Acknowledgment form**
- Step 4 - Check Pregnancy Status**

You must determine if females of reproductive potential are pregnant:

 - One pregnancy test with a sensitivity of at least 25 mIU/mL should be done immediately before starting mycophenolate
 - Another pregnancy test with the same sensitivity should be done 8 to 10 days later
 - Repeat pregnancy tests should be performed at routine follow-up visits
 - Results of all pregnancy tests should be discussed with the patient

In the event of a positive pregnancy test, patients should continue to take mycophenolate until a discussion can take place on the risks and benefits of mycophenolate treatment with the patient.

The patient should be apprised of the potential hazard of the fetus.

In certain situations, you and the patient may decide that the maternal benefits outweigh the risks to the fetus.
- + Step 5 - Report any pregnancies to the Mycophenolate Pregnancy Registry**

Report a Pregnancy

To report a pregnancy, [click here.](#)

Prescriber Training

To view the [Mycophenolate REMS Healthcare Providers Brochure](#), [click here.](#)

Program Materials

[Download or Order materials](#), [click here.](#)

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INFORMATION FOR PRESCRIBERS

What is my role in the Mycophenolate REMS? *Click step to expand details.*

- + **Step 1 - Document your training in the Mycophenolate REMS**
- + **Step 2 - Educate Females of Reproductive Potential**
- + **Step 3 - Obtain a signed Patient-Prescriber Acknowledgment form**
- + **Step 4 - Check Pregnancy Status**

- **Step 5 - Report any pregnancies to the Mycophenolate Pregnancy Registry**

The Mycophenolate Pregnancy Registry has been established to evaluate mycophenolate-exposed pregnancies and their outcomes. These data will provide an opportunity to learn more about mycophenolate exposure in utero.

Instruct patients to tell you if they get pregnant during treatment with mycophenolate or within 6 weeks following discontinuation of treatment.

If you learn that a patient is pregnant:

- Report the pregnancy to the Mycophenolate Pregnancy Registry
 - By phone: **1-800-617-8191**
 - Online by clicking this link [Report a Pregnancy](#)
 - Or by mail: UBC: An Express Scripts Company
200 Pinecrest Plaza,
Morgantown, WV 26505-8065

Patients should be informed that you will report any pregnancies of which you become aware to the Mycophenolate Pregnancy Registry. Provision of patient contact and medical information to the Mycophenolate Pregnancy Registry is covered by a HIPAA waiver.

- Encourage the patient to participate in the Mycophenolate Pregnancy Registry.

Report a Pregnancy
To report a pregnancy, [click here.](#)

Prescriber Training
To view the [Mycophenolate REMS Healthcare Providers Brochure](#), [click here.](#)

Program Materials
[Download or Order materials](#), [click here.](#)

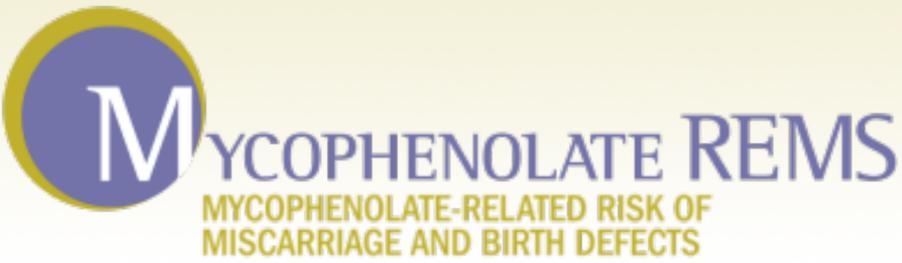
Document Your Training
To [Document Your Training](#), [click here.](#)

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Accessed from Main menu links or Patients button on Home page



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I take mycophenolate, what do I need to know and do?

Click an item below to see more information

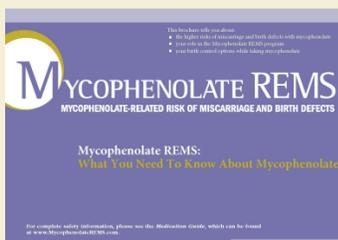
- [+ Understand the risks of taking mycophenolate during pregnancy](#)
- [+ Do I need to use birth control?](#)
- [+ Do I need a pregnancy test?](#)
- [+ What if I am thinking about getting pregnant?](#)
- [+ What if I get pregnant?](#)

Report a Pregnancy
To report a pregnancy, click here.

Program Materials
To view program materials online, click here.

Program Resources and Educational Materials

Your Program Materials:



Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

- For female patients of reproductive potential
- Helps patients understand the program and how to comply with its requirements

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Mycophenolate REMS Patient-Prescriber Acknowledgment

- For prescribers to give to female patients of reproductive potential
- Female patients of reproductive potential must sign this to acknowledge that they will comply with program requirements
- The *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate* also contains a *Mycophenolate REMS Patient-Prescriber Acknowledgment* form

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

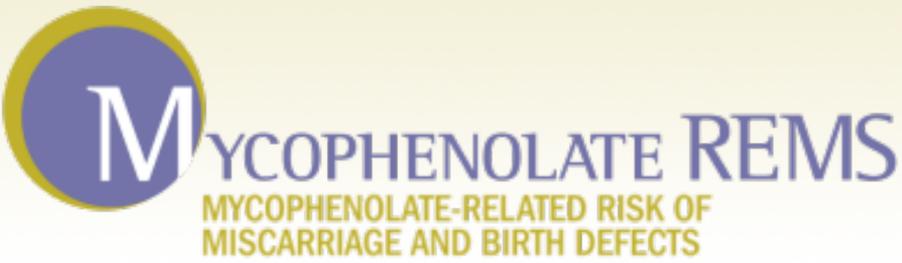
- For prescribers to give to female patients of reproductive potential

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INFORMATION FOR PATIENTS

I take mycophenolate, what do I need to know and do?

Click an item below to see more information

Understanding the risks of taking mycophenolate during pregnancy

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

You need to learn about the risks of mycophenolate in pregnancy:

- Higher risk of losing a pregnancy (miscarriage) during the first 3 months.
- Higher risk that the baby may be born with the birth defects:
 - Defects of the ears
 - Cleft lip or cleft palate
 - Defects of the arms, legs, heart, esophagus, kidney
 - and nervous system

Click here to see complete patient information in the *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate*

- Do I need to use birth control?**
- Do I need a pregnancy test?**
- What if I am thinking about getting pregnant?**
- What if I get pregnant?**

Program Resources and Educational Materials

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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Report a Pregnancy

To report a pregnancy, click here.

Program Materials

To view program materials online, click here.

INFORMATION FOR PATIENTS

I take mycophenolate, what do I need to know and do?

Click an item below to see more information

- [+ Understand the risks of taking mycophenolate during pregnancy](#)
- [+ Do I need to use birth control?](#)

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 forms of birth control.

What are my birth control options? [Print](#)

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 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	Barrier Methods choose 1 <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 <ul style="list-style-type: none"> Diaphragm with spermicide Cervical cap with spermicide Contraceptive sponge 	AND	Barrier Methods choose 1 <ul style="list-style-type: none"> Male condom Female condom

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 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.

- [+ Do I need a pregnancy test?](#)
- [+ What if I am thinking about getting pregnant?](#)
- [+ What if I get pregnant?](#)

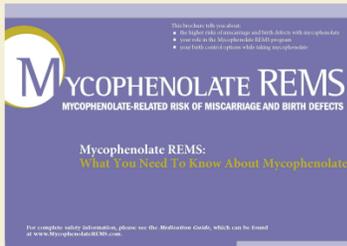
 **Report a Pregnancy**

To report a pregnancy, click [here](#).

 **Program Materials**

To view program materials online, click [here](#).

Your Program Materials:



Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

- For female patients of reproductive potential
- Helps patients understand the program and how to comply with its requirements

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Mycophenolate REMS Patient-Prescriber Acknowledgment

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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INFORMATION FOR PATIENTS

I take mycophenolate, what do I need to know and do?

Click an item below to see more information

- [+ Understand the risks of taking mycophenolate during pregnancy](#)
 - [+ Do I need to use birth control?](#)
 - [+ Do I need a pregnancy test?](#)
- You should have one pregnancy test immediately before starting mycophenolate and another pregnancy test 8 to 10 days later to determine if you are pregnant.
- Pregnancy tests should be repeated during routine follow-up visits with your doctor.
- Talk to your doctor about the results of all your pregnancy tests.
- [+ What if I am thinking about getting pregnant?](#)
 - [+ What if I get pregnant?](#)

 **Report a Pregnancy**

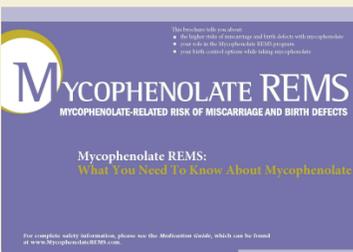
To report a pregnancy, click [here](#).

 **Program Materials**

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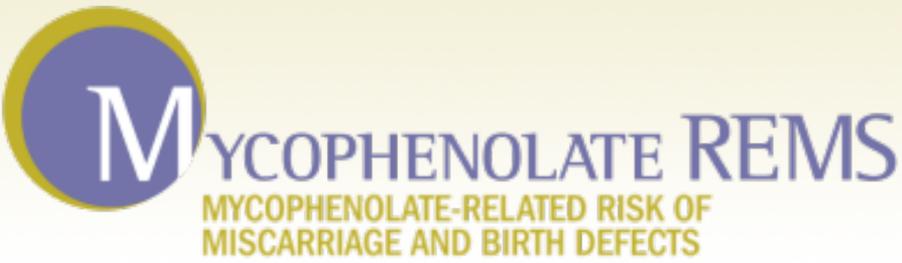
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INFORMATION FOR PATIENTS

I take mycophenolate, what do I need to know and do?

Click an item below to see more information

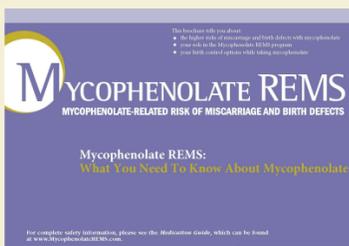
- [+ Understand the risks of taking mycophenolate during pregnancy](#)
 - [+ Do I need to use birth control?](#)
 - [+ Do I need a pregnancy test?](#)
 - [+ What if I am thinking about getting pregnant?](#)
- If you are thinking about having a baby, talk with your doctor right away. Your doctor will decide if other medicines to prevent rejection may be right for you.
- [+ What if I get pregnant?](#)

Report a Pregnancy
To report a pregnancy, click [here](#).

Program Materials
To view program materials online, click [here](#).

Program Resources and Educational Materials

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

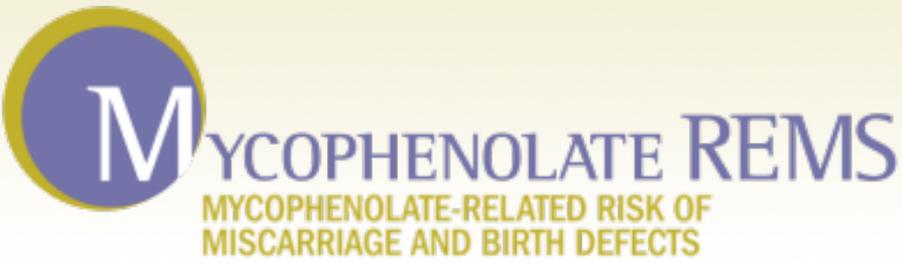
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INFORMATION FOR PATIENTS

I take mycophenolate, what do I need to know and do?

Click an item below to see more information

- + Understand the risks of taking mycophenolate during pregnancy
- + Do I need to use birth control?
- + Do I need a pregnancy test?
- + What if I am thinking about getting pregnant?
- What if I get pregnant?

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 Mycophenolate Pregnancy Registry?

There are 2 ways to report a pregnancy:

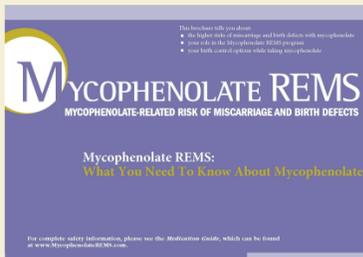
- By phone: **1-800-617-8191**
- Online by clicking this link [Report a Pregnancy](#)



Program Materials

To view program materials online, [click here](#).

Your Program Materials:



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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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Other Healthcare Professionals Overview Page

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INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS?

+ [Step 1](#) - Understand the Risks of Mycophenolate Use During Pregnancy

+ [Step 2](#) - Counsel Females of Reproductive Potential

+ [Step 3](#) - Report Pregnancies

Program Resources and Educational Materials

The Mycophenolate REMS provides the resources and educational materials you need to understand the program and counsel patients.

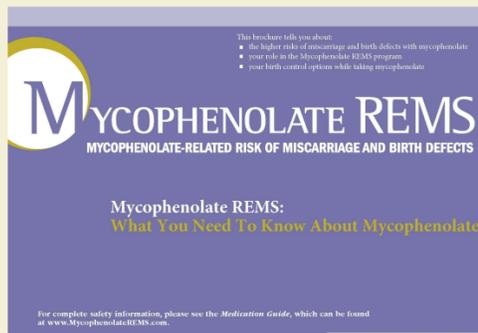
You can view, print, or save the materials to your computer. Select items from the list below.

Your Program Materials:



Mycophenolate REMS Dear Pharmacist Letter

[View to Print or Save](#)



Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

- For prescribers to give to female patients of reproductive potential
- Contains the tools and materials to help patients understand the components of the Mycophenolate REMS
- Includes:
 1. [Mycophenolate REMS Patient-Prescriber Acknowledgment Form](#)

[View to Print or Save](#) | [Order](#)



Mycophenolate REMS Healthcare Providers Brochure

- For prescribers
- Contains information on the risks associated with exposure to mycophenolate during pregnancy, the components of the Mycophenolate REMS, and what you can do to help ensure the successful implementation of the program.

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CellCept Medication Guide

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Generic Mycophenolate Medication Guide

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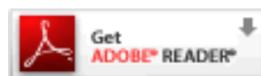
Myfortic Medication Guide

[View to Print or Save](#)

Generic Mycophenolic Acid Medication Guide

[View to Print or Save](#)

The Mycophenolate REMS sponsors attest that this page will only include Medication Guides from the list of approved application numbers and sponsors on the FDA approved REMS website.



INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS?

+ Step 1 - Understand the Risks of Mycophenolate Use During Pregnancy

You should become familiar with the risks of embryofetal toxicity associated with mycophenolate:

- First-trimester pregnancy loss
- Congenital malformations, especially
 - external ear
 - cleft lip and palate abnormalities
- Anomalies of
 - the distal limbs
 - heart
 - esophagus
 - kidney
 - and nervous system

+ Step 2 - Counsel Females of Reproductive Potential

+ Step 3 - Report Pregnancies

Program Resources and Educational Materials

The Mycophenolate REMS provides the resources and educational materials you need to understand the program and counsel patients.

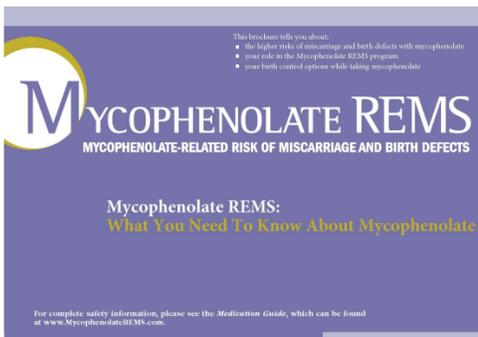
You can view, print, or save the materials to your computer. Select items from the list below.

Your Program Materials:



Mycophenolate REMS Dear Pharmacist Letter

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Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

- For prescribers to give to female patients of reproductive potential
- Contains the tools and materials to help patients understand the components of the Mycophenolate REMS
- Includes:
 1. [Mycophenolate REMS Patient-Prescriber Acknowledgment Form](#)

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Mycophenolate REMS Healthcare Providers Brochure

- For prescribers
- Contains information on the risks associated with exposure to mycophenolate during pregnancy, the components of the Mycophenolate REMS, and what you can do to help ensure the successful implementation of the program.

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CellCept Medication Guide

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Generic Mycophenolate Medication Guide

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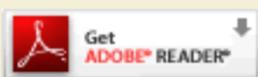
Myfortic Medication Guide

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Generic Mycophenolic Acid Medication Guide

[View to Print or Save](#)

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INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS?

+ [Step 1 - Understand the Risks of Mycophenolate Use During Pregnancy](#)

+ [Step 2 - Counsel Females of Reproductive Potential](#)

Counsel these patients:

With your involvement, we can improve patient understanding and reduce the number of unplanned pregnancies to women taking mycophenolate.

Discuss the following with females of reproductive potential:

- The **increased risks** of first trimester pregnancy loss and congenital malformations while taking mycophenolate.
- **Pregnancy tests** should be conducted before and during mycophenolate treatment.
- **Birth control** needs to be used while taking mycophenolate, and for 6 weeks after stopping treatment, to avoid pregnancy.
- **Pregnancy planning** needs to be discussed with a healthcare provider if a patient wishes to become pregnant during mycophenolate treatment.

The following table lists the forms of contraception that are acceptable for use during treatment with mycophenolate.

[Print](#)

Acceptable Contraception Methods for Females of Reproductive Potential*			
Option 1	Intrauterine devices (IUDs) Tubal sterilization Patient's partner had a vasectomy		
Methods to Use Alone			
OR			
Option 2	Hormone Methods choose 1		Barrier Methods choose 1
Choose One Hormone Method AND One Barrier Method	Estrogen and Progesterone Oral contraceptive pill Transdermal patch Vaginal ring Progesterone-only Injection Implant	AND	Diaphragm with spermicide Cervical cap with spermicide Contraceptive sponge Male condom Female condom
OR			
Option 3	Barrier Methods choose 1		Barrier Methods choose 1
Choose One Barrier Method from each column (must choose two methods)	Diaphragm with spermicide Cervical cap with spermicide Contraceptive sponge	AND	Male condom Female condom

* Females of reproductive potential includes girls who have entered puberty and all women who have a uterus and have not passed through menopause.

Note: Mycophenolate reduces blood levels of the hormones in the oral contraceptive pill and could theoretically reduce its effectiveness. Therefore, an additional barrier method of contraception must be used with all hormonal methods.

EMERGENCY CONTRACEPTION

- Patients should also be counseled on the availability of emergency contraception in the event they have intercourse without acceptable contraception or their contraceptive method fails.
- Patients 17 years and older can purchase emergency contraception over the counter.

+ [Step 3 - Report Pregnancies](#)

Program Resources and Educational Materials

The Mycophenolate REMS provides the resources and educational materials you need to understand the program and counsel patients.

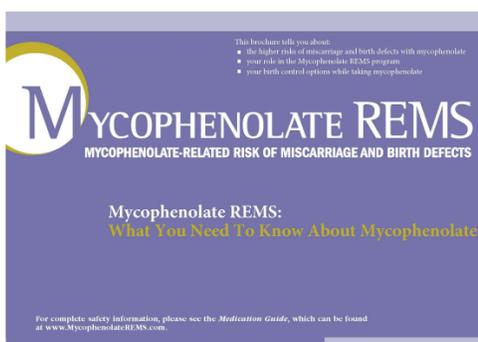
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Your Program Materials:



Mycophenolate REMS Dear Pharmacist Letter

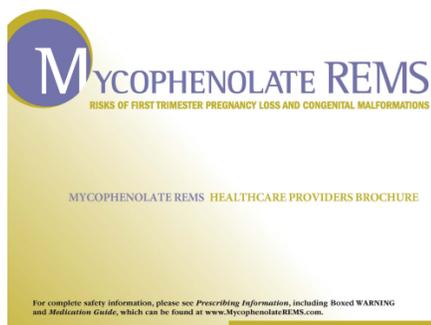
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Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

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INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS?

+ [Step 1 - Understand the Risks of Mycophenolate Use During Pregnancy](#)

+ [Step 2 - Counsel Females of Reproductive Potential](#)

+ [Step 3 - Report Pregnancies](#)

All pregnancies need to be reported to the Mycophenolate Pregnancy Registry.

There are 2 ways to report a pregnancy:

1. **BY PHONE** – You can call the Mycophenolate Pregnancy Registry at 1-800-617-8191
2. **ONLINE** – You can provide your contact information online to the Mycophenolate Pregnancy Registry. Someone from the Mycophenolate Pregnancy Registry will then contact you to confirm necessary healthcare information.

Program Resources and Educational Materials

The Mycophenolate REMS provides the resources and educational materials you need to understand the program and counsel patients.

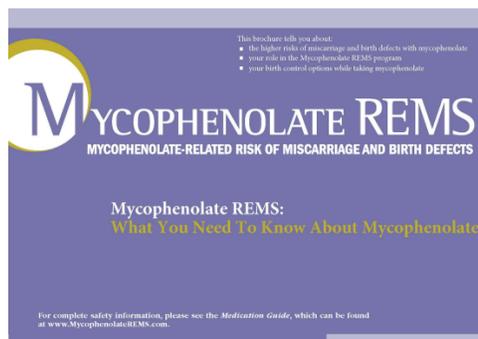
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Your Program Materials:



Mycophenolate REMS Dear Pharmacist Letter

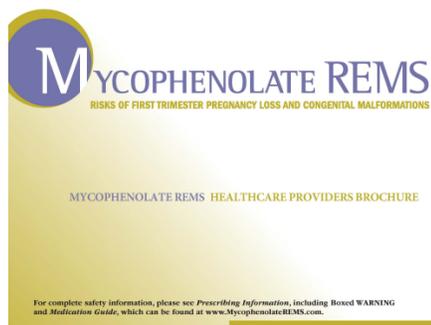
[View to Print or Save](#)



Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

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Generic Mycophenolate Medication Guide

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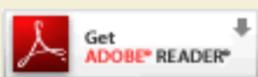
Myfortic Medication Guide

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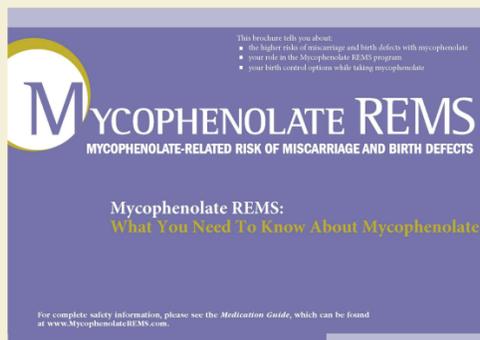


REMS Materials

Accessed from Main menu link on Home Page

Resources and Educational Materials for Prescribers

Your Program Materials:



Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

- For prescribers to give to female patients of reproductive potential
- Contains the tools and materials to help patients understand the components of the Mycophenolate REMS
- Includes:
 1. [Mycophenolate REMS Patient-Prescriber Acknowledgment Form](#)

[View to Print or Save](#) | [Order](#)



Mycophenolate REMS Patient-Prescriber Acknowledgment Form

- For prescribers to give to female patients of reproductive potential
- Female patients of reproductive potential must sign this to acknowledge that they will comply with program requirements
- The *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate*; also contains a *Mycophenolate REMS Patient-Prescriber Acknowledgment Form*

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Mycophenolate REMS Healthcare Providers Brochure

- For prescribers
- Contains information on the risks associated with exposure to mycophenolate during pregnancy, the components of the Mycophenolate REMS, and what you can do to help ensure the successful implementation of the program.

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Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

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Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter for Centers

- For healthcare centers
Contains important information about the Mycophenolate REMS for healthcare centers

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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Mycophenolate REMS Prescriber Training Confirmation Form

- For prescribers
This form can be used to document training in the Mycophenolate REMS. The form can be filled out and mailed or faxed to document your training.

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Mycophenolate REMS OBGYN Referral Letter for Contraceptive Counseling

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Mycophenolate REMS OBGYN Referral Letter for Pre-conception Counseling

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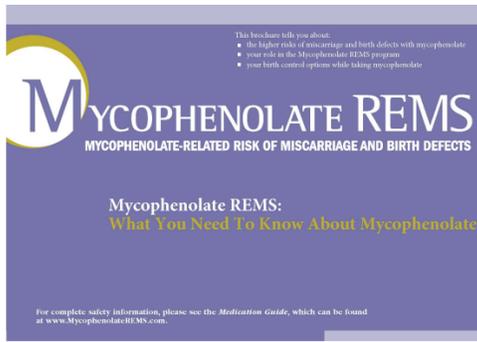
Myfortic Medication Guide

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Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

- For female patients of reproductive potential
- Helps patients understand the program and how to comply with its requirements
-

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Mycophenolate REMS Patient-Prescriber Acknowledgment

- For prescribers to give to female patients of reproductive potential
- Female patients of reproductive potential must sign this to acknowledge that they will comply with program requirements
- The *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate* also contains a *Mycophenolate REMS Patient-Prescriber Acknowledgment* form

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

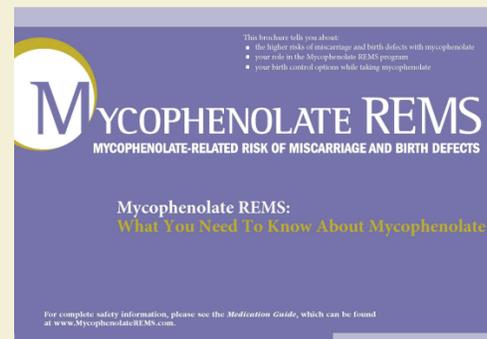
- For prescribers to give to female patients of reproductive potential

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Mycophenolate REMS Dear Pharmacist Letter

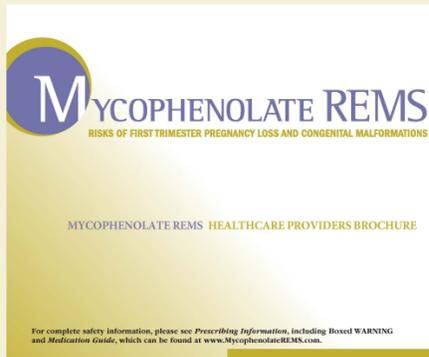
[View to Print or Save](#)



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Generic Mycophenolate Medication Guide

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Myfortic Medication Guide

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Generic Mycophenolic Acid Medication Guide

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Report a Pregnancy Page

Accessed from Main menu links or Report a Pregnancy link in the header or Report a Pregnancy button on Prescriber Overview Page or Report Pregnancy button on Patient Overview Page or Report a Pregnancy button on Pharmacist Overview Page

MYCOPHENOLATE PREGNANCY REGISTRY

How do I report a pregnancy to the Mycophenolate Pregnancy Registry?

There are 2 ways to report a pregnancy:

1. **BY PHONE** – You can call the Mycophenolate Pregnancy Registry at 1-800-617-8191
2. **ONLINE** – You can provide your contact information online to the Mycophenolate Pregnancy Registry. Someone from the Mycophenolate Pregnancy Registry will then contact you to confirm necessary healthcare information.

Patients

I am a pregnant patient, please contact me.

Healthcare Professionals

I am a healthcare professional, please contact me.

What should be reported to the Mycophenolate Pregnancy Registry?

Any pregnancy, planned or unplanned, that occurs:

- While taking mycophenolate or
- Within 6 weeks after stopping treatment.

Who should report a pregnancy to the Mycophenolate Pregnancy Registry?

- **Healthcare Professionals** - Report pregnancies to the Mycophenolate Pregnancy Registry using one of the 2 ways above.
- **Patients** - Tell your doctor if you get pregnant. Do not stop taking your mycophenolate medicine. Your doctor should report the pregnancy to the Mycophenolate Pregnancy Registry.

What is the Mycophenolate Pregnancy Registry?

The Mycophenolate Pregnancy Registry is a way to collect information about pregnancies in female patients taking mycophenolate or within 6 weeks of stopping treatment. 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.

For more information about the Mycophenolate Pregnancy Registry, click one of the links below:

[Patient FAQs](#)

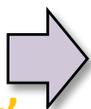
[Prescriber FAQs](#)

I have more questions, where can I get answers?

You can:

- Talk to someone by calling **1-800-617-8191** and selecting the Mycophenolate Pregnancy Registry menu option.

This dialogue box will appear if a user clicks the 'HCP' or 'Patient' report a pregnancy button



Are You Reporting a Pregnancy?

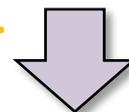
Yes, I have a Pregnancy to Report

No, I need Information about the Registry

No, I Would Like to Return to the Previous Page

For more information, call the Mycophenolate REMS Pregnancy Registry at 1-800-617-8191

If user clicks 'No, I need more information' they are routed to the FAQ page. A new FAQ will be added for prescribers and pharmacists.



NEW FAQ

What information is collected when a pregnancy is registered?

The Mycophenolate REMS Pregnancy Registry actively collects information on all pregnancies that occur during treatment or within 6 weeks of stopping treatment with Mycophenolate. For newly reported and ongoing pregnancies, questions are asked at baseline, first, 2nd and 3rd trimesters, at time of expected delivery and at infant ages 2,6 and 12 months. Data elements include but are not limited to:

- Demographics
- Mycophenolate exposure including dose and timing of exposure
- Maternal and fetal outcomes
- Root cause analysis (understand the circumstances that led to the fetal exposure)
- Frequency of educational counseling
- Infant development to age 12 months

For completed pregnancies, the available information on the pregnancy outcome will be captured and any infant follow-up

Additional Resources Page

Accessed from Main menu links

[Prescriber
Overview](#)

[Patient
Overview](#)

[Other Healthcare
Professionals Overview](#)

[REMS
Materials](#)

[Report a
Pregnancy](#)

[Additional
Resources](#)

[FAQs](#)

ADDITIONAL RESOURCES

FOR MORE INFORMATION ABOUT BIRTH DEFECTS

- Centers for Disease Control and Prevention:*
www.cdc.gov

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 healthcare provider

*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.

You are now leaving the Web site.

Links to external sites are provided as a resource and convenience to our visitors. The Mycophenolate REMS accepts no responsibility for the content of these sites. The Mycophenolate REMS does not control these sites, and the opinions, claims, or comments expressed on these sites should not be attributed to the Mycophenolate REMS.

[Continue](#)

[Cancel](#)

Frequently Asked Questions (FAQs) Page

Accessed from Main menu links

FREQUENTLY ASKED QUESTIONS

▪ Patients

▪ What is the Mycophenolate REMS ?

The Mycophenolate REMS has been designed to tell you about the risks of taking mycophenolate during pregnancy. 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.

▪ Do I have to register in the Mycophenolate REMS as a patient?

Patients do not register in the Mycophenolate REMS.

If you become pregnant during treatment with mycophenolate or within 6 weeks after stopping treatment with mycophenolate, you should inform your doctor and participate in the Mycophenolate Pregnancy Registry. Participation is voluntary; however, the information you provide is important to the success of the program.

The Mycophenolate Pregnancy Registry collects information about pregnancies that occur during treatment with mycophenolate or within 6 weeks after stopping. The information from the Registry helps doctors and patients understand the effects of mycophenolate on pregnant females and their babies.

▪ Do I have to go to a certain pharmacy to get my prescription filled in the Mycophenolate REMS?

You can fill your prescription in any pharmacy.

▪ What forms of birth control should I use while taking mycophenolate?

You should talk with your doctor about what birth control is right for you. You can also get birth control information in the *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate* book. This book is available from your doctor or can be viewed on this Web site.

If you are taking mycophenolate, and you are able to get pregnant, 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.

▪ Where can I find more information about birth control options?

Talk with your doctor about birth control and what is best for you. You can also get birth control information in the *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate* book. This book is available from your doctor and can also be viewed on this Web site.

▪ Where can I find more information about drugs and birth defects?

It is best if you talk with your doctor about your medicines and birth defects.

▪ What type of data is collected by the Mycophenolate Pregnancy Registry and who will see the data?

You can find information on the Registry on this Web site.

The Registry collects information about pregnancies that occur during treatment with mycophenolate or within 6 weeks after stopping. The information from the Registry helps doctors and patients understand the effects of mycophenolate on pregnant females and their babies.

The Registry reports information about an individual female's pregnancy to the maker of the mycophenolate medicine she took. The maker of the drug is required by the law to report the pregnancy to the government.

Summary information (without patient identifiers) may also be shared among makers of mycophenolate medicine who support the Mycophenolate REMS. They may choose to publish it in scientific journals.

▪ Where can I find more information about emergency contraception?

For more information about emergency birth control, talk with your doctor or pharmacist.

- How do I get more information about the Mycophenolate REMS?

You can talk with your doctor for more information.

- What if I become pregnant while on a mycophenolate containing medicine or after I stop taking a mycophenolate containing medicine?

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.

- What is the Mycophenolate Pregnancy Registry?

The Registry collects information about pregnancies that occur during treatment with mycophenolate or within 6 weeks after stopping. The information from the Registry helps doctors and patients understand the effects of mycophenolate on pregnant females and their babies.

- 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 females who took mycophenolate during their pregnancies. 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.

- Who can take part in the Mycophenolate Pregnancy Registry?

All females who are pregnant while taking the following medicines and all females who get pregnant within 6 weeks after stopping treatment:

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

Tell your doctor right away if you get pregnant. Your doctor must 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.

- What will I need to do if I participate 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 with a pre-addressed postage-paid return envelope.
- 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 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 as a participant in the Mycophenolate Pregnancy Registry?

- You can quit at any time
- Your privacy is protected

- Whom can I contact for more information?

- Call **1-800-617-8191** and choose "Mycophenolate Pregnancy Registry" from the menu

- Are there other side effects that I should know about with a mycophenolate containing medicine?

For information on side effects, you can talk with your doctor, ask your pharmacist, read the mycophenolate *Medication Guide* or the *Prescribing Information (PI)*.

- How should I store a mycophenolate containing medicine?

- Store your medication at room temperature (59°F to 86°F).
- Make sure the container is tightly closed.
- Keep mycophenolate and all medicines out of the reach of children.

- In addition to pregnancy, what should I avoid while taking mycophenolate?

For information on what to avoid when taking mycophenolate, talk with your doctor, ask your pharmacist, read the mycophenolate *Medication Guide* or the *Prescribing Information (PI)*.

- How do I handle internet browser issues?

If you are experiencing browser issues, your browser (i.e., Microsoft Internet Explorer, Mozilla Firefox, or Apple Safari) may be blocking the Mycophenolate REMS site, or parts of the Mycophenolate REMS site. You can resolve this by

1. Disabling the pop-up blocker completely every time you need to use the site, or
2. Adding www.MycophenolateREMS.com into your browser's list of allowed sites.

If this does not resolve the issue, it is recommended that you use Internet Explorer 8.0.

- What materials will I receive from my doctor?

- *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate*
This Brochure tells you what you need to know about the Mycophenolate REMS. It explains how the program works and what your role is
- *Mycophenolate REMS Patient-Prescriber Acknowledgment*
After discussion with your doctor about mycophenolate use and risks of miscarriage or birth defects, both of you will sign this form
- *Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients*
Provides answers to frequently asked questions about the Registry

- Prescribers

- Who is Mycophenolate REMS for?

Mycophenolate REMS is designed to help inform prescribers, nurses, pharmacists, and females of reproductive potential of the risks associated with exposure to mycophenolate during pregnancy.

- Who can participate in the Mycophenolate Pregnancy Registry?

A female patient is considered eligible if she meets either of the following criteria:

- A patient who is or was pregnant and was exposed to at least 1 dose of mycophenolate during pregnancy
- A patient who got pregnant within 6 weeks following discontinuation of treatment

Patients who meet either of these criteria, regardless of indication, can participate. Patients whose pregnancy does not meet these criteria may not participate in the Mycophenolate Pregnancy Registry.

- Why is the Mycophenolate Pregnancy Registry important?

Exposure to mycophenolate during pregnancy is associated with:

- Increased risks of pregnancy loss during the first trimester
- Higher risk of congenital malformations
 - Ear abnormalities such as microtia
 - Facial deformities, including cleft lip and palate
 - Anomalies of the distal limbs, heart, esophagus, kidney, and nervous system

The Mycophenolate Pregnancy Registry will collect data to characterize the risks associated with exposure to mycophenolate during pregnancy or within 6 weeks following discontinuation of treatment, regardless of indication. There is no limit to the number or type of physicians and/or patients who may contribute data to the Mycophenolate Pregnancy Registry. All reports of potential maternal and fetal exposure to mycophenolate will be considered for the Mycophenolate Pregnancy Registry.

The success of the Mycophenolate Pregnancy Registry depends on the participation of both patients and healthcare providers. Healthcare providers should identify patients who are currently pregnant or who may have been exposed to mycophenolate while pregnant, inform them of the Mycophenolate Pregnancy Registry, and encourage them to participate in the Mycophenolate Pregnancy Registry. Healthcare providers should report any pregnancy that may involve exposure to

mycophenolate, whether or not the patient chooses to participate. Patients should be informed that you will report any pregnancies of which you become aware to the Mycophenolate Pregnancy Registry.

- What is my role in the Mycophenolate Pregnancy Registry?

Instruct patients to tell you if they get pregnant during treatment with mycophenolate or within 6 weeks following discontinuation of treatment. If you learn that a patient is pregnant.

- Report the pregnancy to the Mycophenolate Pregnancy Registry
- Encourage the patient to participate in the Mycophenolate Pregnancy Registry

When you report an eligible pregnancy to the Mycophenolate Pregnancy Registry, you should provide your contact information. Also provide the Mycophenolate Pregnancy Registry with information about the pregnancy and the patient's contact information so that she can be called for follow-up for this safety study. Provision of patient contact and medical information to the Mycophenolate Pregnancy Registry is covered by an HIPAA waiver.

When patients participate in the Mycophenolate Pregnancy Registry, they agree to provide information about their pregnancy, including information about prenatal drug exposure of any duration, maternal demography and history, and maternal and fetal outcomes of pregnancies exposed to mycophenolate. Patients are encouraged to participate in the Mycophenolate Pregnancy Registry as soon as their pregnancy is known, preferably in the first trimester.

- After I report my patient's pregnancy, what will her participation involve?

The patient will be asked in telephone interviews to answer questions regarding her health and her baby's health. These interviews will take place during each trimester of pregnancy; near the expected time of delivery or at pregnancy outcome; and when the infant reaches 2 months, 6 months, and 1 year of age. Since the Mycophenolate Pregnancy Registry relies on being able to contact the patient, it is important for you to advise her to keep the Mycophenolate Pregnancy Registry informed of any changes to her contact information throughout her participation.

- After I enroll my patient, what is my role?

You will be asked to provide pregnancy and outcomes data on a paper-based case report form (CRF) and submit it via mail or fax, or enter the data into an electronic data capture (EDC) system. You must keep the Mycophenolate Pregnancy Registry informed of any changes to your contact information throughout your participation.

- How will data collected by the Mycophenolate Pregnancy Registry be analyzed and reported?

The Mycophenolate Pregnancy Registry program administrator will report personally identifiable pregnancy data to the appropriate drug manufacturer for purposes of reporting to regulatory agencies as required by law. Aggregated de-identified data may be shared among participating sponsors of Mycophenolate REMS and/or submitted for publication in peer-reviewed scientific journals.

- How can I obtain more information?

- Visit www.MycophenolateREMS.com
- Call 1-800-617-8191

- Pharmacists

- Do pharmacies have to register with the program?

No. Pharmacies do not register in the Mycophenolate REMS. Pharmacies are required to provide patients with the medication guide for a particular mycophenolate product when dispensing the drug.

- Does a pharmacy have to do anything special before filling a prescription?

The only requirement for pharmacies in the Mycophenolate REMS is to provide the patient with a medication guide when dispensing mycophenolate.

- How can I order more medication guides?

Additional medication guides can be ordered over the phone (1-800-617-8191).

- Will Mycophenolate REMS patients have a special card or ID Number?

No. Patients in the Mycophenolate REMS do not have cards or ID numbers.

- Can I accept mycophenolate prescriptions by phone, fax or email?

Yes. The Mycophenolate REMS does not affect a pharmacy's policy on how a prescription is received. You can accept a mycophenolate prescription by any means you would accept any other prescriptions.

- Email

- Add Mycophenolate REMS to your safe senders

Listed below are steps to help with receiving emails from Mycophenolate REMS.

Because email clients differ, and spam filters sometimes filter legitimate email, Mycophenolate REMS suggests you add the

Mycophenolate REMS domain to your Safe Senders list in your email client. This will minimize the chance that you'll miss Mycophenolate REMS emails.

For Outlook 2000 and Higher

1. Open the email from Mycophenolate REMS.
2. Click on the "Actions" menu on the top of your email window.
3. Choose "Junk Email."
4. Select "Add Senders Domain...to Safe Senders List" to add Mycophenolate REMS to your safe sender list.

Or Follow These Steps

1. Open the email from Mycophenolate REMS.
2. Right-click Mycophenolate REMS email address.
3. Click "Add to Contacts" in the short-cut menu.
4. Click "Save and Close."

Outlook Express (6+)

1. Open the email from Mycophenolate REMS.
2. Left-click Mycophenolate REMS icon, or right-click Mycophenolate REMS name.
3. Click "Add to Contacts."
4. Click "Save and Close."

AOL 9.0

1. Open the email from Mycophenolate REMS.
2. Click the "Add Address" icon.
3. Verify Mycophenolate REMS contact information.
4. Save it.

AOL WebMail

1. Open the email from Mycophenolate REMS.
2. Click on Mycophenolate REMS name and email address.
3. Click "Add to Address Book" in the window that appears.
4. Enter extra information as needed.
5. Click "Save."

Earthlink

1. Open the email from Mycophenolate REMS.
2. Click "Add to Address Book" in the email header.
3. Use the "Address Book Editor" to verify Mycophenolate REMS contact details, and click "Save."

Entourage

1. Open the email from Mycophenolate REMS.
2. Right-click Mycophenolate REMS email address.
3. Select "Add to Address Book" in the short-cut menu.
4. Verify Mycophenolate REMS contact details.
5. Click "Save."

Gmail

1. Open the email from Mycophenolate REMS.
2. Click "More Options" in the email header.
3. Click "Add Sender to Contacts List."

Hotmail

1. Open the email from Mycophenolate REMS.
2. Click “Save Address” in the toolbar.
3. Verify Mycophenolate REMS contact details.
4. Click “ok.”

* Users may also white-list Mycophenolate REMS entire domain (everything behind the @ sign) using the “Safe List” feature under Options → Mail → Junk Email Protection.

Yahoo!

1. Open the email from Mycophenolate REMS.
2. Click “Add to Address Book” to the right, next to Mycophenolate REMS name.
3. Verify Mycophenolate REMS contact details.
4. Click “Add to Address Book.”

MacMail

1. Open the email from Mycophenolate REMS.
2. Ctr-click Mycophenolate REMS email address and select “Open in Address Book.”
3. Verify Mycophenolate REMS contact details.



Tell a Colleague Page

Accessed from Tell a Colleague link in the header

[Prescriber Overview](#)

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TELL A COLLEAGUE

**Denotes a required field.*

From (your name)* :

Your email* :

Your colleague's email* :

Email message will be as follows:

Hi,
I thought you'd be interested in learning about the Mycophenolate REMS on the MycophenolateREMS.com Web site. Just click the link below (or copy and paste the link into your browser).
<https://www.MycophenolateREMS.com>

This information is used only for the purpose of sending this email.

Prescriber Documentation of Training

Accessed from Enroll button on Prescriber Overview page

[Prescriber Overview](#)

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PRESCRIBER TRAINING

Please enter your email, this will act as your user name.
If you already have an account please login.

Email :

Re-type Email :

PRESCRIBER TRAINING

Prescriber Training Confirmation

Read and acknowledge the following statements:

The FDA determined that a REMS (Risk Evaluation and Mitigation Strategy) is necessary to ensure that the benefits of mycophenolate outweigh the increased risks of first trimester pregnancy loss and congenital malformations associated with mycophenolate use during pregnancy.

Mycophenolate is available by prescription as

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

As a prescriber of mycophenolate to female patients of reproductive potential,* I understand that I complete this Mycophenolate REMS Training Confirmation Form to document my training in the Mycophenolate REMS.

*A female of reproductive potential includes girls who have entered puberty and all females who have a uterus and have not passed through menopause.

I agree to do the following:

1. Read and understand *Prescribing Information* for mycophenolate and the *Mycophenolate REMS Healthcare Providers Brochure*.
2. Understand the increased risks of first trimester pregnancy loss and congenital malformations associated with mycophenolate.
3. Educate females of reproductive potential on the risks associated with exposure to mycophenolate during pregnancy.
4. Provide a *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate* booklet to females of reproductive potential.
5. Provide contraceptive counseling to patients directly or by partnering with an OB/GYN.
6. Only prescribe mycophenolate to a pregnant patient if the benefits of initiating or continuing treatment outweigh the risk of fetal harm.
7. Discuss alternative treatments to mycophenolate with females of reproductive potential who are pregnant or considering pregnancy.
8. Follow the pregnancy testing recommendations as outlined in the *Prescribing Information* for mycophenolate and the *Mycophenolate REMS Healthcare Providers Brochure*.
9. Report to the Mycophenolate Pregnancy Registry any pregnancies that occur during mycophenolate treatment or within 6 weeks following discontinuation of treatment. Encourage pregnant patients to participate in the Mycophenolate Pregnancy Registry.
10. Obtain a signed *Mycophenolate REMS Patient-Prescriber Acknowledgment* form from each female of reproductive potential.

I understand that I may be contacted in the future for items pertaining to the administration of the Mycophenolate REMS.

I acknowledge that by completing this Mycophenolate REMS Prescriber Training Confirmation Form I attest to follow the Mycophenolate REMS requirements outlined above.

<< Back

Continue >>

Cancel

PRESCRIBER TRAINING

Please supply the following information about yourself and then select Continue. This address will be your primary address.
(NOTE: Address verification will be performed on the entered address)

**Denotes a required field.*

Institution :

First Name* :

Last Name* :

Address1* :

Address2 :

City* :

State* :

ZIP* :

Phone* : () -

FAX : () -

NPI Number* :

Degree* :

Specialty* :

You can provide the name of a staff member; for example, a nurse, who may act on your behalf.

Authorized Staff Members

[+ Add Staff](#)

[<< Back](#)

[Continue >>](#)

[Cancel](#)

[| Legal Statement |](#)

PRESCRIBER TRAINING

Please supply the following information about yourself and then select Continue. This address will be your primary address.
(NOTE: Address verification will be performed on the entered address)

**Denotes a required field.*

Institution :

First Name* :

Last Name* :

Address1* :

Address2 :

City* :

State* :

ZIP* :

Phone* : ()

FAX : ()

NPI Number* :

Degree* :

Specialty* :

You can provide the name of a staff member; for example, a nurse, who may act on your behalf.

Authorized Staff Members

[+ Add Staff](#)

Add/Edit Staff Members Information

First Name* :

Last Name* :

Email* :

Degree* :

Specialty* :

[Save](#) [Cancel](#)

<< Back

Continue >>

Cancel

[| Legal Statement |](#)

PRESCRIBER TRAINING

Please confirm that the information you entered is correct and select Continue to go to the next step or select Back to correct your information.

(NOTE: Please review the address carefully as the address validation process may have changed or standardized the address you entered)

Address : Doctor Doctor
110 Main St
Hatboro, PA 19040

Authorized Staff Members

Phone : (555)555-5555
Degree : MD
Specialty : Cardiology
NPI Number : 1578555462

<< Back

Continue >>

Cancel

| [Legal Statement](#) |

PRESCRIBER TRAINING

You may maintain two mailing addresses in the Mycophenolate REMS for ordering additional program materials. You may add another address at a later time if you choose not to add one now.

Would you like to add another mailing address now?

Yes

No

[<< Back](#)

[Continue >>](#)

[Cancel](#)

| [Legal Statement](#) |

PRESCRIBER TRAINING

Please provide your additional mailing address information and then select Continue.
(NOTE: Address verification will be performed on the entered address)

**Denotes a required field.*

Institution :	<input type="text"/>
Address1* :	<input type="text"/>
Address2 :	<input type="text"/>
City* :	<input type="text"/>
State* :	<input type="text"/>
ZIP* :	<input type="text"/>
Phone* :	(<input type="text"/>) <input type="text"/> - <input type="text"/>
FAX :	(<input type="text"/>) <input type="text"/> - <input type="text"/>

[| Legal Statement |](#)

PRESCRIBER TRAINING

Please confirm that the information you entered is correct and select Continue to go to the next step or select Back to correct your information.

(NOTE: Please review the address carefully as the address validation process may have changed or standardized the address you entered)

Address : 123 Easton St
 Blue Bell, PA 12345

Phone : (987)654-3211

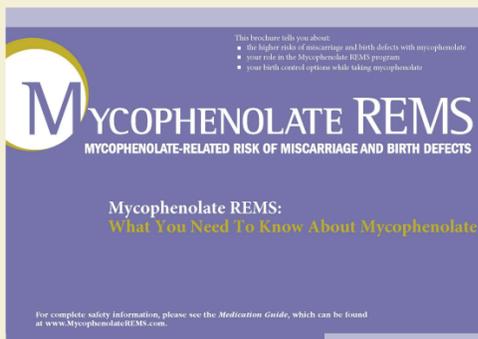
[| Legal Statement |](#)

PRESCRIBER TRAINING

As part of the process to document your training, you are able to order the Mycophenolate REMS materials that you will need to get started in the program. You will be able to order more materials after you document your training.

Select a quantity(Qty) for each item that you want to order:

Your Program Materials:

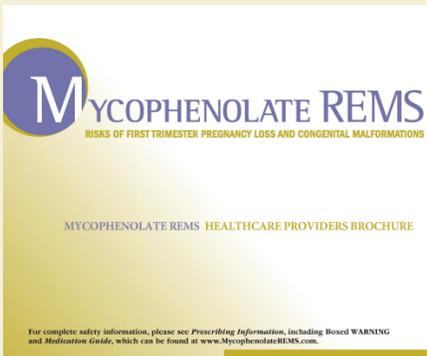


Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

Qty:

2

- For prescribers to give to female patients of reproductive potential
- Contains the tools and materials to help patients understand the components of the Mycophenolate REMS
- Includes:
 1. [Mycophenolate REMS Patient-Prescriber Acknowledgment form](#)



Mycophenolate REMS Healthcare Providers Brochure

Qty:

1

- For prescribers
- Contains information on the risks associated with exposure to mycophenolate during pregnancy, the components of the Mycophenolate REMS, and what you can do to help ensure the successful implementation of the program.

<< Back

Continue >>

Cancel

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PRESCRIBER TRAINING

Set your password.

Username is your email address : doctor@yahoo.com

Password : ?

Confirm Password :

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PRESCRIBER TRAINING

Dan Smith, you are now successfully enrolled in the Mycophenolate REMS.

- You will receive an email confirmation of your current enrollment.
IMPORTANT : Add email@MycophenolateREMS.com to your Safe Senders list to ensure that you receive this confirmation. (See [Instructions on adding Mycophenolate REMS to your Safe Senders](#))

[Finish](#)

[Order Program Materials](#)

Prescriber Login

Accessed from Prescriber Login link in the header of Prescriber Overview Page

Login Credentials ✕

Prescriber Login

Email :

Password :

[Login](#) [Cancel](#)

[Forgot Password](#) [Privacy Statement](#)

**Bold and increase font:
“Continue without logging
in”**

Login Credentials

You are not currently logged on. If you log on, profile information is passed on to external site automatically. **Continue without logging in.**

Prescriber Login

Email :

Password :

[Forgot Password](#) [Privacy Statement](#)

Add dialogue box

For privacy reasons, we cannot collect patient medical information on this form.

After you submit the form below, someone from the Mycophenolate Pregnancy Registry will contact you via your preferred method within 1 business day.

To report a pregnancy over the phone, you may contact the registry at 1-800-617-8191.

Forgot Password

Accessed from Prescriber Login Screen as a link

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[Other Healthcare Professionals Overview](#)

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INFORMATION FOR PRESCRIBERS

What is my role in the Mycophenolate REMS Program?

- + [Step 1 - Document your training](#)
- + [Step 2 - Educate Females of Reproductive Age](#)
- + [Step 3 - Obtain a signed Patient-Prescriber Acknowledgment form](#)
- + [Step 4 - Check Pregnancy Status](#)
- + [Step 5 - Report any pregnancies to the Mycophenolate Pregnancy Registry](#)

Do prescribers have to be trained in the Mycophenolate REMS in order to prescribe mycophenolate-containing products?

Healthcare professionals are not required to complete the *Mycophenolate REMS Prescriber Training Confirmation Form* in order to prescribe mycophenolate-containing medicines. However, healthcare professionals who prescribe mycophenolate-containing medicines will be contacted by the Mycophenolate REMS Program and encouraged to review the program materials and complete a *Mycophenolate REMS Prescriber Training Confirmation Form* (online or paper).

Forgot Password

Email :

[Retrieve Password](#) [Cancel](#)

[<< Back to Login](#) [Privacy Statement](#)

[Report a Pregnancy](#)
To report a pregnancy, click here.

[Prescriber Training](#)
To view the Mycophenolate REMS Healthcare Providers Brochure, click here.

[Program Materials](#)
Download or Order materials, click here.

[Document Your Training](#)
To Document Your Training, click here.

Prescriber Order Materials

Accessed by clicking To order online button under Program Materials section on Prescriber Overview page or by clicking on Order link next to each Program material

[Prescriber Overview](#)

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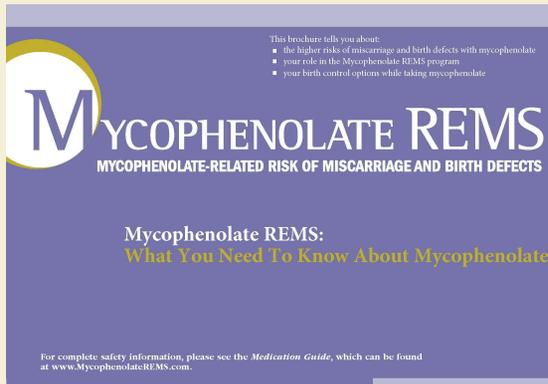
[FAQs](#)

ORDER MATERIALS

Step 1 of 4: Select Materials

Select a quantity(Qty) for each item that you want to order:

Your Program Materials:



Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

Qty:

0

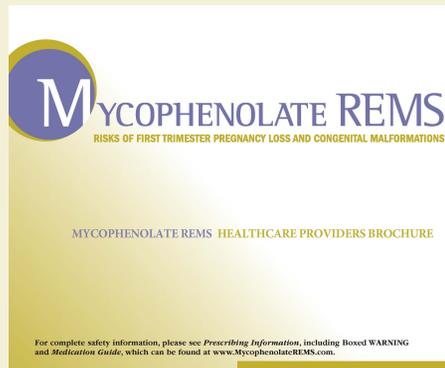
- For prescribers to give to female patients of reproductive potential
- Contains the tools and materials to help patients understand the components of the Mycophenolate REMS
- Includes:
 1. [Mycophenolate REMS Patient-Prescriber Acknowledgment form](#)



Mycophenolate REMS Patient-Prescriber Acknowledgment

Qty: 0

- For prescribers to give to female patients of reproductive potential
- Female patients of reproductive potential must sign this to acknowledge that they will comply with program requirements
- The *Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate* also contains a *Mycophenolate REMS Patient-Prescriber Acknowledgment* form



Mycophenolate REMS Healthcare Providers Brochure

Qty: 0

- For prescribers
- Contains information on the risks associated with exposure to mycophenolate during pregnancy, the components of the Mycophenolate REMS, and what you can do to help ensure the successful implementation of the program.



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

Qty: 0

- For prescribers to give to female patients of reproductive potential



Mycophenolate REMS Prescriber Training Confirmation Form

Qty:

0

- For prescribers
- This form can be used to document training in the Mycophenolate REMS. The form can be filled out and mailed or faxed to document your training.

Continue >>

Cancel

| [Legal Statement](#) | Intended for U.S. Audiences Only

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ORDER MATERIALS

Step 2 of 4: Select Shipping Address

Please select a shipping address.

- Attn: Test_Shilpa
123 test
blue bell, PA 19021
- Attn: TestD
123 Street Name
Blue Bell, PA 19403
- Enter Different Shipping Address

<< Back

Continue >>

Cancel

ORDER MATERIALS

Step 3 of 4: Confirm Order Information

(NOTE: Please review the address carefully as the address validation process may have changed or standardized the address you entered)

Review and confirm your order information :

Ordered Items	
Qty	Item
1	Mycophenolate REMS Prescriber Training Confirmation Form

Shipping Information
Shipping Address :
Attn: Test_Shilpa Test_Koduri
123 test
blue bell, PA 19021
Contact Information :
Phone : (111) 111-1111

ORDER MATERIALS

Step 4 of 4: Order Completed

Order Complete

Your order has been completed, and will ship via Fedex within 5 business days. You will receive an email confirmation of the order.

IMPORTANT! : To ensure that you receive this email, it is important that you add noreply@MycophenolateREMS.com to your list of safe senders in your email. Please see [Instructions on adding Mycophenolate REMS to your Safe Senders](#)

If you do not receive this email in your inbox, please check your SPAM or junk mail folder.

[Finish](#)



Welcome **Test_User**

[Edit My Profile](#) | [Logout](#)

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ORDER MATERIALS

Step 4 of 4: Order Completed

Order Complete

Your order has been completed, and will ship via Fedex within 5 business days.
You will receive an email confirmation of the order.

IMPORTANT! : To ensure that you receive this email, it is important that you add noreply@MycophenolateREMS.com to your list of safe senders in your email. Please see [Instructions on adding Mycophenolate REMS to your Safe Senders](#)

If you do not receive this email in your inbox, please check your SPAM or junk mail folder.

[Finish](#)

Edit My Profile

Accessed from Edit My Profile link in the header (Visible only when Prescriber is logged in)

VIEW AND EDIT MY PROFILE

▲ Professional Information		Hide Details...
NPI Number : 111111112	Edit	
Degree : MD	Edit	
Specialty : Cardiology	Edit	
▲ Staff Member Information		Hide Details...
You can provide the name of a staff member; for example, a nurse, who may act on your behalf.		
Authorized Staff Members		+ Add Staff
test test_name, PA Family Practitioner test@staffmember.com	Edit Delete	
▲ Other Information		Hide Details...
Email : shilpa.koduri@unitedbiosource.com	Edit	
Password : *****	Edit	
▲ Addresses		Hide Details...
Primary Address	Secondary Address	
Institution :	Institution :	
Attn First Name : Test_Shilpa	Attn First Name : TestD	
Attn Last Name : Test_Koduri	Attn Last Name : TestD	
Address1 : 123 test	Address1 : 123 Street Name	
Address2 :	Address2 :	
City : blue bell	City : Blue Bell	
State : PA	State : PA	
ZIP : 19021	ZIP : 19403	
Phone : (111) 111-1111	Phone : (123) 123-1233	
FAX :	FAX :	
Edit	Edit Delete	

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

OZLEM A BELEN
11/13/2015