

Risk Evaluation and Mitigation Strategy (REMS) Document

Mycophenolate Shared System REMS Program

I. Administrative Information

Initial Shared System REMS Approval: 9/2012

Most Recent REMS Updated: 01/2021

II. REMS Goal

The goal of the Mycophenolate REMS is to mitigate the risk of embryo-fetal 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 pregnancy loss (miscarriage) and birth defects
 - The importance of pregnancy prevention and planning when taking mycophenolate

III. REMS Requirements

Mycophenolate Applicants must provide training to healthcare providers who prescribe mycophenolate.

The training must include all the elements of the [FDA Blueprint](#).

For training provided by Mycophenolate Applicants, the training includes the following educational material: [Healthcare Provider Brochure](#).

For training provided by Continuing Education (CE) Providers, training is compliant with the REMS if it: 1) is offered by an accredited CE Provider and supported by independent commercially-supported educational grants from the Mycophenolate Applicants; 2) includes, at a minimum, a knowledge assessment of all sections of the [FDA Blueprint](#); and 3) is subject to independent audit to confirm that conditions of the REMS training have been met.

To inform healthcare providers about the REMS and the risks and safe use of mycophenolate, Mycophenolate Applicants must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials & Dissemination Plans
Healthcare providers who prescribed mycophenolate at least once in the 12 months prior to the date of	REMS Letter: Dear Healthcare Provider Letter 1 <ol style="list-style-type: none">1. Email within 60 calendar days of the approval of the REMS modification (01/15/2021). If a healthcare provider's email address is not available, send by mail.

Target Audience

Communication Materials & Dissemination Plans

the REMS modification approval

- a. For first emails marked unopened: Send a second email within seven (7) calendar days of the date the first email was sent.
- b. For second emails marked unopen: Send by mail within 30 calendar days of the date that the second email was sent.
- c. For emails that are undeliverable: Send by mail within 30 calendar days of the date that the first set of emails were sent.

REMS Letter: [Dear Healthcare Provider Letter 2](#)

2. Email when accredited continuing education is available and no later than 12 months following REMS modification approval. If a healthcare provider's email address is not available, send by mail.
 - a. For first emails marked unopened: Send a second email within seven (7) calendar days of the date the first email was sent.
 - b. For second emails marked unopen: Send by mail within 30 calendar days of the date that the second email was sent.
 - c. For emails that are undeliverable: Send by mail within 30 calendar days of the date that the first set of emails were sent

All transplant centers

REMS Letter: [Dear Healthcare Provider Letter for Centers 1](#)

1. Mail within 60 calendar days of the approval of the REMS modification (01/15/2021).

REMS Letter: [Dear Healthcare Provider Letter for Centers 2](#)

2. Mail when accredited continuing education is available and no later than 12 months following REMS modification approval (01/15/2021).

All newly identified healthcare providers who prescribed mycophenolate at least once in the prior 12 months

REMS Letter: [Dear Healthcare Provider Letter 1](#)

1. Email within 60 calendar days of the date the healthcare provider is newly identified from the approval of the REMS modification until accredited continuing education is available.
 - a. Send a second email within seven (7) calendar days of the date the first email was sent if the first email is marked as unopened.
 - b. Send by mail within 30 calendar days of the date that the second email was sent if the second email is marked as unopened.
 - c. Send by mail within 30 calendar days of the date that the first set of emails were sent if a healthcare provider's email address is not available or the email is undeliverable.

REMS Letter: [Dear Healthcare Provider Letter 2](#)

1. After accredited continuing education is available: email within 60 calendar days of the date the healthcare provider is newly identified.
 - a. Send a second email within seven (7) calendar days of the date the first email was sent if the first email is marked as unopened.
 - b. Send by mail within 30 calendar days of the date that the second email was sent if the second email is marked as unopened.
 - c. Send by mail within 30 calendar days of the date that the first set of emails were sent if a healthcare provider's email address is not available or the email is undeliverable.

Healthcare providers who are likely to prescribe

[Website Banner](#)

1. Publish quarterly for 30 calendar days for the first 12 months after

Target Audience

Communication Materials & Dissemination Plans

mycophenolate

approval of the REMS modification, then every 6 months for 2 years through the following professional societies and their associated journals:

- a. American College of Rheumatology, American Society of Transplantation, American College of Physicians, American Academy of Neurology, American College of Obstetricians and Gynecologists, American Society of Nephrology

To support REMS operations, Mycophenolate Applicants must:

1. Establish and maintain a REMS website, www.mycophenolaterems.com. The REMS website must include a current list of training funded by the Mycophenolate Applicants the capability for healthcare providers to confirm that they have completed training, order patient education materials, and to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS website. The REMS website must not link back to the promotional product websites.
2. Make the REMS website fully operational and all REMS materials available through the website and call center within 60 calendar days of REMS modification approval on 01/15/2021.
3. Establish and maintain a REMS call center for healthcare providers at 1-800-617-8191.
4. Direct CE Providers to the [FDA Blueprint](https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mycophenolate_2021_01_15_FDA_Blueprint_for_Mycophenolate_REMS_Education.pdf) on https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mycophenolate_2021_01_15_FDA_Blueprint_for_Mycophenolate_REMS_Education.pdf
5. Ensure healthcare providers are able to order the [Patient Information Brochure: What You Need to Know About Mycophenolate](#) and [Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients](#) online and by phone.
6. Ensure healthcare providers are able to access training no later than 12 months following approval of the REMS modification (01/15/2021).
7. Ensure healthcare providers are able to report completion of training online and by mail, email, and fax using the [Prescriber Training Confirmation Form](#).
8. Ensure designees of transplant centers are able to report that healthcare providers at the center have completed training by mail, email, and fax using the [Center Training Confirmation Form](#).
9. Establish and maintain a validated, secure database of all healthcare providers and centers that report completing training.
10. Monitor distribution and prescription data monthly to identify new mycophenolate prescribers who need to be trained.
11. Notify accredited CE Providers of REMS-compliant training regarding changes to the [FDA Blueprint](#) within 10 calendar days of such changes.
12. Use independent auditors (accreditation bodies of CE Providers are considered independent and eligible to conduct the audits) to audit the educational materials used by the accredited CE Providers of REMS-compliant training funded by the Mycophenolate Applicants to evaluate (1) whether the content of the training addresses all the elements of the FDA Blueprint, (2) whether the knowledge assessment measures knowledge of all sections of the FDA Blueprint, (3) whether the training was conducted in accordance with the standards for commercially-supported CE of the Accreditation Council for Continuing Medical Education or of another CE accrediting body appropriate to prescribers.
13. Establish and maintain a registry which includes a reporting and collection system for females who become pregnant and consent to participate to provide information on maternal and fetal outcomes.
14. Ensure that once a report suggestive of pregnancy is received, a Mycophenolate Applicant follows up with the healthcare provider to obtain all required data for the registry.

IV. REMS Assessment Timetable

Mycophenolate NDA Applicants must submit REMS Assessments 18 months from the date of the REMS modification approval and every 18 months thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. The Mycophenolate NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Mycophenolate REMS:

Training and Educational Materials

Healthcare Provider:

1. Healthcare Provider training available at www.mycophenolaterems.com
2. [Healthcare Provider Brochure](#)

Patient:

3. [Patient Information Brochure: What You Need to Know About Mycophenolate](#)
4. [Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients](#)

Communication Materials

5. [Dear Healthcare Provider Letter 1](#)
6. [Dear Healthcare Provider Letter 2](#)
7. [Dear Healthcare Provider Letter for Centers 1](#)
8. [Dear Healthcare Provider Letter for Centers 2](#)
9. [Website Banner](#)

Other Materials

10. [Program website \(www.mycophenolaterems.com\)](http://www.mycophenolaterems.com)
11. [Mycophenolate REMS Education Blueprint for Healthcare Providers Who Prescribe \(FDA Blueprint\)](#)
12. [Prescriber Training Confirmation Form](#)
13. [Center Training Confirmation Form](#)



HEALTHCARE PROVIDER BROCHURE

What you need to know about mycophenolate use, first trimester pregnancy loss, and congenital malformations.

What is my role in the Mycophenolate REMS?

1	Document your training in the Mycophenolate REMS
2	Educate Females of Reproductive Potential on the increased risks of mycophenolate
3	Check pregnancy status of patients
4	Reassess treatment options for patients who are considering becoming pregnant
5	Report any pregnancies to the Mycophenolate Pregnancy Registry

For complete safety information and a comprehensive description of the increased risks associated with mycophenolate, please see *Prescribing Information*, including Boxed WARNING and *Medication Guide*, which can be found at www.MycophenolateREMS.com

MYCOPHENOLATE AND INCREASED RISKS OF EMBRYOFETAL TOXICITY

There are increased risks of first trimester pregnancy loss and congenital malformations associated with mycophenolate. As a healthcare provider, here is what you should know.

MYCOPHENOLATE PREGNANCY RISKS



- 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, but not limited to:
 - the distal limbs, heart, esophagus, kidney, nervous system

MYCOPHENOLATE REMS

- The Food and Drug Administration (FDA) requires a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of taking a drug outweigh the serious risks.
- The Mycophenolate REMS is required due to post marketing reports showing that exposure to mycophenolate during pregnancy is associated with increased risks of first trimester pregnancy loss and congenital malformations.
- Mycophenolate is available by prescription as:
 - ▶ CellCept® (mycophenolate mofetil), Myfortic® (mycophenolic acid), Generic mycophenolate mofetil, Generic mycophenolic acid.

HEALTHCARE PROVIDER INFORMATION



- All prescribers of mycophenolate and females of reproductive potential, whether or not they plan to get pregnant, should be aware of the increased risks associated with mycophenolate.
- Females of reproductive potential include girls who have entered puberty and all women who have a uterus and ovaries and have not passed through menopause.
- Menopause is the permanent end of menstruation and fertility, and should be clinically confirmed by a patient's healthcare practitioner. Commonly used diagnostic criteria include:
 - ▶ 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or therapy)
 - ▶ Post-surgical from a bilateral oophorectomy

DATA INSIGHTS

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[†]:

- 25 had spontaneous abortions
- 14 had a malformed fetus or infant, of which six had ear abnormalities

While available data are limited, structural malformations occur in approximately 20% of live-born infants exposed in utero to mycophenolate. First trimester pregnancy loss rates have been reported to be approximately 45%*[†].

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

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

MYCOPHENOLATE AND INCREASED RISKS OF EMBRYOFETAL TOXICITY

As a healthcare provider, you need to complete the following five steps to help ensure the implementation of Mycophenolate REMS with females of reproductive potential:

1 DOCUMENT YOUR REMS TRAINING

- Become familiar with the increased risks of embryofetal toxicity associated with mycophenolate and the requirements of the Mycophenolate REMS
- Consider enrolling in an accredited CME/CE activity to further understand your role in the treatment of patients taking mycophenolate products. A full list of CME/CE providers can be found at MycophenolateREMS.com
- Complete and submit the online *Prescriber Training Confirmation Form* to document that you understand, and will comply with the Mycophenolate REMS requirements. Submit your form by:
 - ▶ Visiting MycophenolateREMS.com
 - ▶ Calling 1-800-617-8191, Faxing a hard copy to 1-800-617-5768, or emailing a copy to support@mycophenolateREMS.com
 - ▶ Mailing a hard copy to Mycophenolate REMS 200 Pinecrest Plaza, Morgantown, WV 26505-9065

2 EDUCATE FEMALES OF REPRODUCTIVE POTENTIAL

- Educate females about the increased risks of mycophenolate exposure during pregnancy
- Provide females of reproductive potential with a *Patient Information Brochure: What You Need To Know About Mycophenolate* and review it with them.
- Provide pregnancy planning education
- 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
 - Emergency contraception

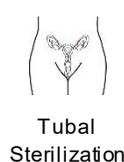
ACCEPTABLE BIRTH CONTROL OPTIONS

Guide your patients to choose from the following birth control options for use during treatment with mycophenolate:

Option 1 | Use Method Alone

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

A



Option 2 | Use Hormone & Barrier

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

B



Option 3 | Use Two Barriers

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

C



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

MYCOPHENOLATE AND INCREASED RISKS OF EMBRYOFETAL TOXICITY

3 CHECK PREGNANCY STATUS

- 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 increased 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 increased risks to the fetus.

4 REASSESS TREATMENT OPTIONS FOR PATIENTS WHO ARE CONSIDERING BECOMING PREGNANT

- Determine whether there are appropriate treatment options with less potential for embryofetal toxicity.
- Refer patients for pre-conception counseling and high-risk obstetrical care as needed and coordinate care among the patient's established providers.

5 REPORT MYCOPHENOLATE-EXPOSED PREGNANCIES

- 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:
 - ▶ Visiting MycophenolatePregnancyRegistry.com
 - ▶ Calling 1-800-617-8191
 - ▶ Mailing information to Mycophenolate Pregnancy Registry
200 Pinecrest Plaza, Morgantown, WV, 26505-8065
- Inform your patient 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.

ADDITIONAL RESOURCES

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

- Patient Information Brochure
- Prescriber Training Confirmation Form
- Center Training Confirmation Form
- Medication Guides
- Mycophenolate Pregnancy Registry Frequently Asked Questions (FAQs) for Patients
- Contraception: plannedparenthood.org
- Birth Defects: CDC.gov
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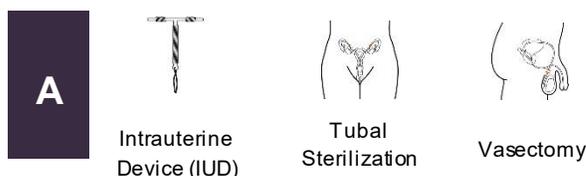
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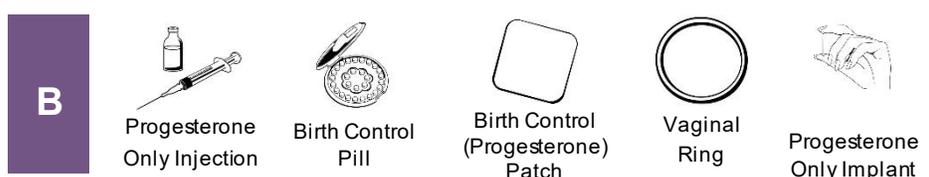
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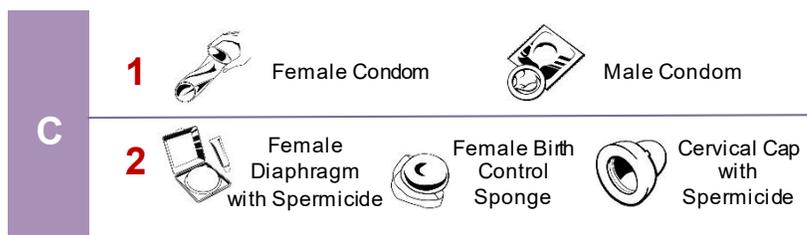
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- Pick one item from (C1) **and** one from (C2)
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5 REPORT MYCOPHENOLATE-EXPOSED PREGNANCIES

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ADDITIONAL RESOURCES

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

- Patient Information Brochure
- Prescriber Training Form
- Center Training Confirmation Form
- Medication Guides
- Mycophenolate Pregnancy Registry Frequently Asked Questions (FAQs) for Patients
- Contraception: plannedparenthood.org
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PATIENT INFORMATION BROCHURE

What you need to know about mycophenolate use and pregnancy risk

What is my role in the Mycophenolate REMS?

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

To learn more about the serious risks of taking Mycophenolate, please see the *Medication Guide*, which can be found at www.MycophenolateREMS.com

MYCOPHENOLATE AND INCREASED RISKS OF MISCARRIAGE AND BIRTH DEFECTS

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

WHAT ARE THE RISKS WITH MYCOPHENOLATE?



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

WHAT IS THE MYCOPHENOLATE REMS?

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

DATA INSIGHTS

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

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

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

Of the 77 females who took mycophenolate during pregnancy[†]:

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

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

WHAT DO I NEED TO KNOW ABOUT PREGNANCY PREVENTION?

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

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

[†]Prescribing Information for mycophenolate.

To learn more about all the risks of taking mycophenolate, please see the Medication guide, which can be found at MycophenolateREMS.com

MYCOPHENOLATE AND INCREASED RISKS OF MISCARRIAGE AND BIRTH DEFECTS

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

1 TALK WITH YOUR DOCTOR

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

2 CHOOSE A BIRTH CONTROL OPTION

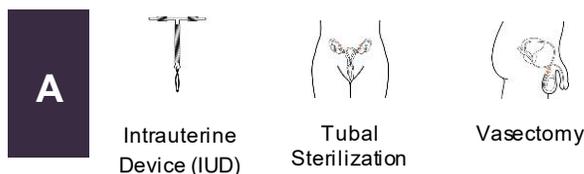
- Choosing birth control is very personal. Talk with your doctor or obstetrician/gynecologist to decide what is best for you. Unless you choose not to have sexual intercourse with a man at any time (abstinence), you must use acceptable birth control for your entire treatment with mycophenolate and for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

ACCEPTABLE BIRTH CONTROL OPTIONS

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

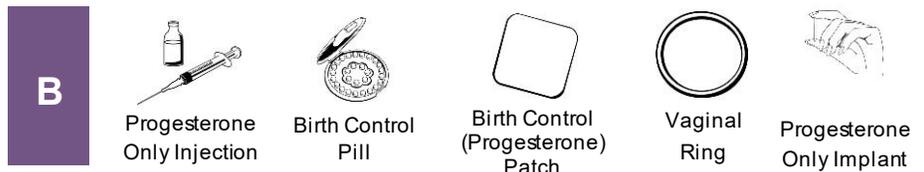
Option 1 | Use Method Alone

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



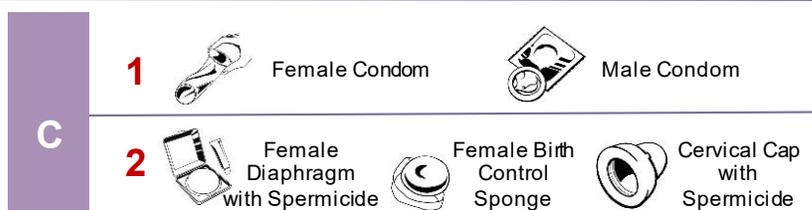
Option 2 | Use Hormone & Barrier

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



Option 3 | Use Two Barriers

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



To learn more about all the risks of taking mycophenolate, please see the Medication guide, which can be found at MycophenolateREMS.com

MYCOPHENOLATE AND INCREASED RISKS OF MISCARRIAGE AND BIRTH DEFECTS

3 GET A PREGNANCY TEST

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

IMPORTANT INFORMATION

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

RESOURCES FOR YOU

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

- **Medication Guide for mycophenolate**
 - ▶ Gives you important safety information you need to know about your medicine.
- **Your doctor or other healthcare provider**
- **MycophenolateREMS.com**
 - ▶ 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 MycophenolatePregnancyRegistry.com
- **Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients**
 - ▶ Provides answers to frequently asked questions about the Registry. You can get this from your healthcare provider or by visiting: MycophenolateREMS.com
 - ▶ Birth Control: plannedparenthood.org
 - ▶ Birth Control: FDA.gov

MYCOPHENOLATE AND RISK OF EMBRYOFETAL TOXICITY

Increased risks of first trimester
pregnancy loss and
congenital malformations



[CLICK HERE TO LEARN MORE](#)

Mycophenolate REMS Website Screenshots

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

Looking for Accredited REMS CME/CE Activities?

[Click here](#)

What is the Mycophenolate REMS?

The Mycophenolate REMS is a program to tell doctors, nurses, pharmacists, and patients about the increased 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?

Prescribers

For Prescriber Overview,
[click here](#)

Patients

For Patient Overview,
[click here](#)

Other Healthcare Professionals

For Other Healthcare
Professionals, [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 miscarriage and birth defects 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 pregnancy loss (miscarriage) and birth defects.
 - The importance of pregnancy prevention and planning when taking mycophenolate.

What medications contain mycophenolate?

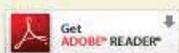
Mycophenolate Mofetil
CellCept® by Genentech USA, Inc.

[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 ovaries and have not passed through menopause.



CME/CE Activities Page

Accessed from the banner on the Home Page, Prescriber Overview Page,
and Other Healthcare Professional Page



ACCREDITED REMS CME/CE ACTIVITIES

The goal of the Mycophenolate REMS is to mitigate the risk of embryofetal toxicity associated with the use of mycophenolate 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 pregnancy loss (miscarriage) and birth defects.
 - The importance of pregnancy prevention and planning when taking mycophenolate.

As part of the Mycophenolate REMS, the Mycophenolate Applicants must provide training for healthcare providers who prescribe and/or participate in the treatment of patients taking mycophenolate products. This training includes accredited CME/CE activities developed by accredited CME/CE Providers and offered to healthcare providers at no cost.

The FDA has developed a FDA Blueprint for the Mycophenolate REMS, which contains a high-level outline of the core educational messages that must be addressed in the educational programs developed under the Mycophenolate REMS. The core messages are directed to healthcare providers who prescribe and/or participate in the treatment of patients taking mycophenolate products.

A list of available REMS CME/CE activities offered by accredited CME/CE Providers and supported by independent commercially-supported educational grants from the Mycophenolate Applicants appears below. To access these accredited CME/CE activities, click on any link in the Table below.

Program Title	Accredited CME/CE Provider	Link to CME/CE Activity

The Mycophenolate Applicants attest that this table will be populated once grants are approved and will include the list of available CME/CE activities.

Prescriber Overview Page

Accessed from Main menu links or Prescribers button on Home Page

INFORMATION FOR PRESCRIBERS

Looking for Accredited REMS CME/CE Activities?
[Click here](#)

Prescriber Training
 To view the Healthcare Provider Brochure, and document your training, [click here](#).

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

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 increased 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 *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/email it to:

Mycophenolate REMS
 200 Pinecrest Plaza
 Morgantown, WV 26505-8065
support@mycophenolatere.ms.com

- Call 1-800-617-8191

Step 2 - Educate Females of Reproductive Potential

Step 3 - Check Pregnancy Status

Step 4 - Report any pregnancies to the Mycophenolate Pregnancy Registry

DATA INSIGHTS

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†:

- 25 had spontaneous abortions
- 14 had a malformed fetus or infant, of which six had ear abnormalities

While available data are limited, structural malformations occur in approximately 20% of live-born infants exposed in utero to mycophenolate. First trimester pregnancy loss rates have been reported to be approximately 45%†.

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

Healthcare providers are not required to complete the *Prescriber Training Confirmation Form* in order to prescribe mycophenolate-containing medicines. However, healthcare providers who prescribe mycophenolate-containing medicines will be contacted by the Mycophenolate REMS and encouraged to become trained. This training could include reading the *Prescribing Information* and the *Healthcare Provider Brochure* or attending an accredited continuing education (CE) training program. As part of the REMS, the manufacturers of mycophenolate products have provided unrestricted grants to support CME/CE activities regarding risks associated with mycophenolate use during pregnancy. **A full list of CME/CE providers can be found on this website.**

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 REMS materials:

1. **ONLINE** – You can order the materials online. [To Order Online, click here](#)
2. **BY PHONE** – 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 REMS Materials:



Patient Information 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

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



Healthcare Provider 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](#)



Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

[View to Print or Save](#)



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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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](#)



CellCept Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

[View to Print or Save](#)

Generic Medication Guides

Drug Name	Generic Name	Company	Links

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

*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.



INFORMATION FOR PRESCRIBERS

Looking for Accredited REMS CME/CE Activities?

[Click here](#)

Prescriber Training

To view the Healthcare Provider Brochure, and document your training, [click here](#).

REMS Materials

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DATA INSIGHTS

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:

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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†:

- 25 had spontaneous abortions
- 14 had a malformed fetus or infant, of which six had ear abnormalities

While available data are limited, structural malformations occur in approximately 20% of live-born infants exposed in utero to mycophenolate. First trimester pregnancy loss rates have been reported to be approximately 45%†.

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 increased risks of mycophenolate exposure during pregnancy. Discuss the increased risks of miscarriage and birth defects 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 *Patient Information Brochure: What You Need To Know About Mycophenolate*.

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

Patients need to understand:

- the increased risks of miscarriage and birth defects while using mycophenolate
- their birth control options
- their role in the Mycophenolate REMS

- 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-conceptional 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](#)

ACCEPTABLE BIRTH CONTROL OPTIONS

Guide your patients to choose from the following birth control options for use during treatment with mycophenolate:

<p>Option 1 Use Method Alone</p> <ul style="list-style-type: none"> Pick one item from (A) Most effective: Less than 1 pregnancy per 100 women in one year 	<p>A</p>
<p>Option 2 Use Hormone & Barrier</p> <ul style="list-style-type: none"> Pick one item from (B) and one item from (C1) or (C2) shown below 4-7 pregnancies per 100 women in one year 	<p>B</p>
<p>Option 3 Use Two Barriers</p> <ul style="list-style-type: none"> Pick one item from (C1) and one from (C2) Least effective: 13 or more pregnancies per 100 women in one year 	<p>C</p>

Note: Mycophenolate lowers 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. For complete safety information, please see Prescribing Information, including boxed WARNING and Medication Guide, which can be found at [MycophenolateREMS.com](#)

* Females of reproductive potential includes girls who have entered puberty and all women who have a uterus and ovaries 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.

Step 3 - Check Pregnancy Status

Step 4 - 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 providers are not required to complete the *Prescriber Training Confirmation Form* in order to prescribe mycophenolate-containing medicines. However, healthcare providers who prescribe mycophenolate-containing medicines will be contacted by the Mycophenolate REMS and encouraged to become trained. This training could include reading the *Prescribing Information* and the *Healthcare Provider Brochure* or attending an accredited continuing education (CE) training program. As part of the REMS, the manufacturers of mycophenolate products have provided unrestricted grants to support CME/CE activities regarding risks associated with mycophenolate use during pregnancy. **A full list of CME/CE providers can be found on this website.**

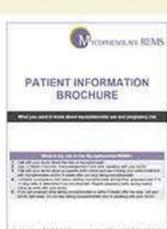
Program Resources and Educational Materials

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 REMS materials:

- ONLINE – You can order the materials online. [To Order Online, click here](#)
- BY PHONE – You can order materials by calling the Mycophenolate REMS call center at 1-800-617-8191.
- 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 REMS Materials:



Patient Information 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

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



Healthcare Provider 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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Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

[View to Print or Save](#)



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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Prescriber Training Confirmation Form

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CellCept Medication Guide

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Myfortic Medication Guide

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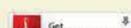
Generic Medication Guides

Drug Name	Generic Name	Company	Links

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INFORMATION FOR PRESCRIBERS

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[Click here](#)

Prescriber Training

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REMS Materials

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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 - 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 increased 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 increased risks to the fetus.

Step 4 - Report any pregnancies to the Mycophenolate Pregnancy Registry

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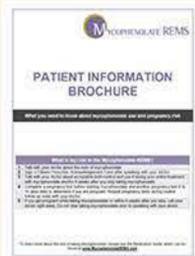
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Dear Healthcare Provider (DHCP) Letter

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- Contains important information about the Mycophenolate REMS

[View to Print or Save](#)



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](#)



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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Prescriber Training Confirmation Form

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CellCept Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

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Drug Name	Generic Name	Company	Links

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INFORMATION FOR PRESCRIBERS

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To view the Healthcare Provider Brochure, and document your training, [click here](#).

REMS Materials

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

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

- 1 **Step 1 - Document your training in the Mycophenolate REMS**
- 2 **Step 2 - Educate Females of Reproductive Potential**
- 3 **Step 3 - Check Pregnancy Status**
- 4 **Step 4 - 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 become 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
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 and encourage patients to read the [Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients](#) on this website

DATA INSIGHTS

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:

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Of the 77 females exposed to systemic mycophenolate during pregnancy that were reported in postmarketing data†:

- 25 had spontaneous abortions
- 14 had a malformed fetus or infant, of which six had ear abnormalities

While available data are limited, structural malformations occur in approximately 20% of live-born infants exposed in utero to mycophenolate. First trimester pregnancy loss rates have been reported to be approximately 45%†.

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

Healthcare providers are not required to complete the *Prescriber Training Confirmation Form* in order to prescribe mycophenolate-containing medicines. However, healthcare providers who prescribe mycophenolate-containing medicines will be contacted by the Mycophenolate REMS and encouraged to become trained. This training could include reading the *Prescribing Information* and the *Healthcare Provider Brochure* or attending an accredited continuing education (CE) training program. As part of the REMS, the manufacturers of mycophenolate products have provided unrestricted grants to support CME/CE activities regarding risks associated with mycophenolate use during pregnancy. **A full list of CME/CE providers can be found on this website.**

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 REMS materials:

- ONLINE** – You can order the materials online. [To Order Online, click here](#)
- BY PHONE** – You can order materials by calling the Mycophenolate REMS call center at 1-800-617-8191.
- 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 REMS Materials:



Patient Information 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

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



Healthcare Provider 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](#)



Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

[View to Print or Save](#)



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](#)



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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



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](#)



CellCept Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

[View to Print or Save](#)

Generic Medication Guides

Drug Name	Generic Name	Company	Links

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†Prescribing Information for mycophenolate.



Patient Overview Page

Accessed from Main menu links or Patients button on Home Page

INFORMATION FOR PATIENTS

I take mycophenolate, what do I need to know and do? *Click an item below to expand details.*

Understanding the increased 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 increased risks of mycophenolate during pregnancy.

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

- Higher risk of 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 *Patient Information 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?

Report a Pregnancy

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

REMS Materials

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

DATA INSIGHTS

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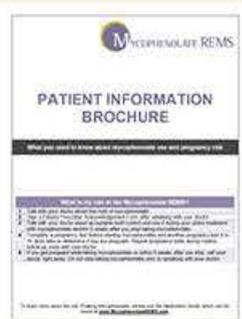
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Program Resources and Educational Materials

Your REMS Materials:



Patient Information 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

[View to Print or Save](#)



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 expand details*

Understanding the increased 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

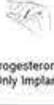
Unless you choose not to have sexual intercourse with a man at any time (abstinence), you must always use acceptable forms of birth control.

What are my birth control options?

[Print](#)

ACCEPTABLE BIRTH CONTROL OPTIONS

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

Option 1 Use Method Alone Pick one item from (A) ▶ Most effective: Less than 1 pregnancy per 100 women in one year	A	 Intrauterine Device (IUD)	 Tubal Sterilization	 Vasectomy		
Option 2 Use Hormone & Barrier Pick one item from (B) and one item from (C1) or (C2) shown below ▶ 4-7 pregnancies per 100 women in one year	B	 Progesterone Only Injection	 Birth Control Pill	 Birth Control (Progesterone) Patch	 Vaginal Ring	 Progesterone Only Implant
Option 3 Use Two Barriers Pick one item from (C1) and one from (C2) ▶ Least effective: 13 or more pregnancies per 100 women in one year	C	1  Female Condom	2  Female Diaphragm with Spermicide	1  Male Condom	2  Female Birth Control Sponge	2  Cervical Cap with Spermicide

To learn more about all the risks of taking mycophenolate, please see the Medication guide, which can be found at mycophenolateREMS.com

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

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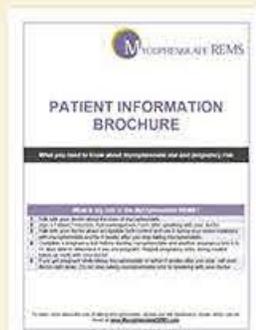
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INFORMATION FOR PATIENTS

I take mycophenolate, what do I need to know and do? *Click an item below to expand details.*

➤ **Understanding the increased 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](#).

REMS Materials

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DATA INSIGHTS

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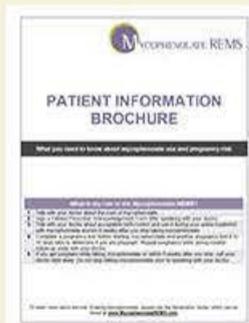
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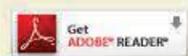
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INFORMATION FOR PATIENTS

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- ⊕ Understanding the increased 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](#).

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

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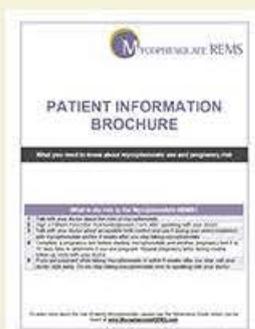
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INFORMATION FOR PATIENTS

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- Understanding the increased 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](#)

Report a Pregnancy

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

REMS Materials

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DATA INSIGHTS

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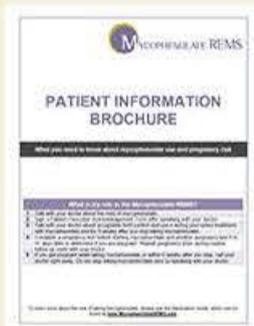
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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

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Other Healthcare Professionals Overview Page

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button on Home Page

INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

Looking for Accredited REMS CME/CE Activities?
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DATA INSIGHTS

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What do I need to know about the Mycophenolate REMS? [Click step to expand details](#)

- Step 1 - Understand the Increased Risks of Mycophenolate Use During Pregnancy**

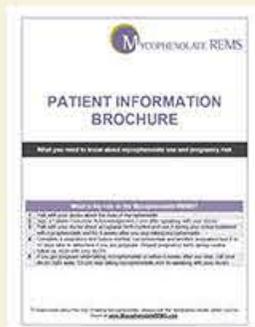
You should become familiar with the increased risks of embryofetal toxicity associated with mycophenolate:

 - 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 REMS Materials:



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Healthcare Provider Brochure

- For prescribers

[View to Print or Save](#)



CellCept Medication Guide

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Myfortic Medication Guide

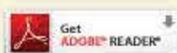
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Generic Medication Guides

Drug Name	Generic Name	Company	Links

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What do I need to know about the Mycophenolate REMS? [Click step to expand details.](#)

➔ **Step 1 - Understand the Increased 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 in women taking mycophenolate.

Discuss the following with females of reproductive potential:

- The increased risks of miscarriage and birth defects 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 BIRTH CONTROL OPTIONS

Guide your patients to choose from the following birth control options for use during treatment with mycophenolate:

Option 1 | Use Method Alone

■ Pick one item from (A)

- Most effective: Less than 1 pregnancy per 100 women in one year

A



Option 2 | Use Hormone & Barrier

■ Pick one item from (B) **and** one item from (C1) or (C2) shown below

- 4-7 pregnancies per 100 women in one year

B

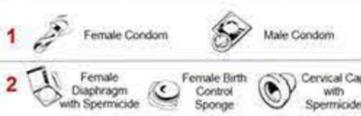


Option 3 | Use Two Barriers

■ Pick one item from (C1) **and** one from (C2)

- Least effective: 13 or more pregnancies per 100 women in one year

C



Note: Mycophenolate induces 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. For complete safety information, please see Prescribing Information, including boxed WARNING and Medication Guide, which can be found at [MycophenolateREMS.com](#)



* Females of reproductive potential includes girls who have entered puberty and all women who have a uterus and ovaries 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.

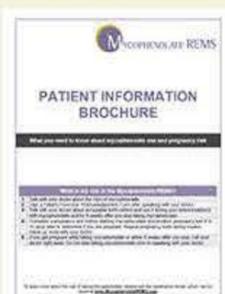
➔ **Step 3 - Report Pregnancies**

Program Resources and Educational Materials

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[View to Print or Save](#)



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What do I need to know about the Mycophenolate REMS? [Click step to expand details.](#)

- **Step 1 - Understand the Increased 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.
- [Report a Pregnancy](#)

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Generic Medication Guides

Drug Name	Generic Name	Company	Links

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

*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.



REMS Materials

Accessed from Main menu link on Home Page



MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS
AND CONGENITAL MALFORMATIONS

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MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS AND CONGENITAL MALFORMATIONS

Prescribers

Resources and Educational Materials for Prescribers

Your REMS Materials:



Patient Information 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

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



Healthcare Provider 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](#)



Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

[View to Print or Save](#)



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](#)



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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



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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CellCept Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

[View to Print or Save](#)

Generic Medication Guides

Drug Name	Generic Name	Company	Links

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

Patients

Resources and Educational Materials for Patients

Your REMS Materials:



Patient Information 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

[View to Print or Save](#)



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

[View to Print or Save](#)

Other Healthcare Professionals

Resources and Educational Materials for Other Healthcare Professionals

Your REMS Materials:



Patient Information 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

[View to Print or Save](#)



Healthcare Provider 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](#)



CellCept Medication Guide

[View to Print or Save](#)



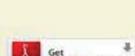
Myfortic Medication Guide

[View to Print or Save](#)

Generic Medication Guides

Drug Name	Generic Name	Company	Links

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



Report a Pregnancy Page



- [Prescriber Overview](#)
- [Patient Overview](#)
- [Other Healthcare Professionals Overview](#)
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- [Report a Pregnancy](#)
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- [FAQs](#)
- [For CME/CE Community](#)

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.

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 below.
- **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.

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.

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.

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.

Patients

I am a pregnant patient, please contact me.

Healthcare Professionals

I am a healthcare professional, please contact me.



- [Prescriber Overview](#)
- [Patient Overview](#)
- [Other Healthcare Professionals Overview](#)
- [REMS Materials](#)
- [Report a Pregnancy](#)
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- [For CME/CE Community](#)

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 report a pregnancy to the Mycophenolate Pregnancy Registry online. If you are someone from the Mycophenolate

[Patient Overview](#)
I am a contact

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

What should be reported to the Mycophenolate Pregnancy Registry?

Any pregnancy, planned or unplanned, that occurs:

- While taking mycophenolate
- 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



Report a Pregnancy



Please provide the contact information requested below. Required fields are indicated by an asterisk (*)

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.

Patient Contact Information

First Name* :

Last Name* :

Address 1* :

Address 2 :

City* :

State* :

ZIP* :

Email Address :

Primary Phone Number* :

Secondary Phone Number :

Fax Number :

Preferred Contact Method* :

Healthcare Provider Contact Information

First Name :

Last Name :

Address 1 :

Address 2 :

City :

State :

ZIP :

Email Address :

Primary Phone Number :

Secondary Phone Number :

Fax Number :

Preferred Contact Method :

[Patient FAQs](#)

[Prescriber FAQs](#)

I have more questions, where can I get answers?

You can:

Reference ID: 4732128

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

Report a Pregnancy Page

HCP Not Logged In

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 below
- **Patients** - Tell your doctor or pharmacist. Your doctor or pharmacist will report to the Registry.

How do I report a pregnancy?

There are 2 ways to report a pregnancy:

1. **BY PHONE** - You can call 1-800-368-7777
2. **ONLINE** - You can pre-register on the Mycophenolate Pregnancy Registry. See the "How to Register" page for more information. We will contact you to confirm the pregnancy.

What should be reported?

Any pregnancy, planned or unplanned, should be reported.

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

Healthcare Professionals

I am a healthcare professional, please contact me.

Login Credentials



You are not currently logged on. If you log on, profile information is passed on to the pregnancy registry. [Continue without logging in.](#)

Prescriber Login

Email :

Password :

Login

Cancel

[Forgot Password](#)

[Privacy Statement](#)



[Prescriber Overview](#)

[Patient Overview](#)

[Other Healthcare Professionals Overview](#)

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MYCOPHENOLATE PREGNANCY REGISTRY

Report a Pregnancy



Please provide the contact information requested below. Required fields are indicated by an asterisk (*)

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.

Healthcare Provider Contact Information

First Name* :

Last Name* :

Address 1* :

Address 2 :

City* :

State* :

ZIP* :

Email Address :

Primary Phone Number* :

Secondary Phone Number :

Fax Number :

Preferred Contact Method* :

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.

Additional Resources Page

Accessed from Main menu links



[Prescriber Overview](#) | [Patient Overview](#) | [Other Healthcare Professionals Overview](#) | [REMS Materials](#) | [Report a Pregnancy](#) | [Additional Resources](#) | [FAQs](#) | [For CME/CE Community](#)

ADDITIONAL RESOURCES

FOR MORE INFORMATION ABOUT BIRTH DEFECTS

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

FOR MORE INFORMATION ABOUT BIRTH CONTROL

- Planned Parenthood:*
www.plannedparenthood.org
- Food and Drug Administration:
www.fda.gov/consumers/free-publications-women/birth-control

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 *Patient Information Brochure: What You Need To Know About Mycophenolate* brochure. This brochure is available from your doctor or can be viewed on this website.

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 *Patient Information Brochure: What You Need To Know About Mycophenolate* brochure. This brochure is available from your doctor and can also be viewed on this website.

- 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 website.

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?

You can also contact Planned Parenthood at 1-800-230-PLAN (1-800-230-7526), online at www.plannedparenthood.org or text "PPNOW" to 774636 (PPINFO) to get answers (standard message and data rates may apply).

- 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 mycophenolate mofetil
- Generic mycophenolic acid

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

- 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?

- *Patient Information 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 Pregnancy Registry Frequently Asked Questions for Patients*
Provides answers to frequently asked questions about the Registry.

- **Prescribers**

- Who is the 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?

- 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 and encourage patients to read the *Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients* on this website

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 a 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 applicants of Mycophenolate REMS and/or submitted for publication in peer-reviewed scientific journals.

- Do I still report pregnancies to the National Transplantation Pregnancy Registry (NTPR)?

All pregnancies occurring during treatment with mycophenolate or within 6 weeks following discontinuation of treatment should be reported to the Mycophenolate Pregnancy Registry, regardless of indication, for inclusion and follow-up. In addition to reporting exposed pregnancies to the Mycophenolate Pregnancy Registry, you may also report pregnancies to the NTPR.

- How can I obtain more information?

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

- 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

- **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.

- **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

- **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.



For CME/CE Community

Accessed from Main menu links

FOR THE CME/CE COMMUNITY

Accredited REMS CME/CE Activities for Mycophenolate

The goal of the Mycophenolate REMS is to mitigate the risk of embryofetal toxicity associated with the use of mycophenolate 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 pregnancy loss (miscarriage) and birth defects
 - The importance of pregnancy prevention and planning when taking mycophenolate.

Links

[\[Year\] Request for Application \(RFA\)](#)

As part of the Mycophenolate REMS, the Mycophenolate Applicants must provide education for healthcare providers who prescribe and/or participate in the treatment of patients taking mycophenolate products.

The FDA has developed a FDA Blueprint for the Mycophenolate REMS, which contains a high-level outline of the core educational messages that must be addressed in the educational programs developed under the Mycophenolate REMS. The core messages, which are directed to healthcare providers who prescribe and/or participate in the treatment of patients taking mycophenolate products, include:

- The increased risks of miscarriage and birth defects associated with mycophenolate.
- Importance of educating females of reproductive potential about the increased risk of miscarriage and birth defects associated with exposure to mycophenolate during pregnancy.
- Importance of prescribers providing or facilitating patient education about pregnancy prevention and planning, including acceptable methods of contraception during mycophenolate treatment.
- When treating a pregnant patient or a patient who is considering pregnancy, consider alternative immunosuppressants with less potential for embryofetal toxicity
- Importance of reporting to the Mycophenolate Pregnancy Registry any pregnancies that occur during mycophenolate treatment or within 6 weeks following discontinuation of treatment.
- Importance of encouraging pregnant patients to participate in the Mycophenolate Pregnancy Registry.
- Importance of obtaining a signed Patient-Prescriber Acknowledgement Form from each female of reproductive potential.

In order to expand the educational reach of training on the Mycophenolate REMS, the Mycophenolate Applicants will make available Request for Applications (RFA) for independent commercially-supported educational grants. If the submission window for a given grant cycle is open, the RFA will be available in the right column of this webpage, which includes additional details related to the submission of a grant application. Additionally, a list of Mycophenolate Applicants-supported accredited CME/CE activities and the accredited CME/CE Providers offering the activity can be referenced below:

Program Title	Accredited CME/CE Provider

The Mycophenolate Applicants attest that this table will be populated once grants are approved.

Tell a Colleague Page

Accessed from Tell a Colleague link in the header



- [Prescriber Overview](#)
- [Patient Overview](#)
- [Other Healthcare Professionals Overview](#)
- [REMS Materials](#)
- [Report a Pregnancy](#)
- [Additional Resources](#)
- [FAQs](#)
- [For CME/CE Community](#)

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 website. Please copy and paste the link into your browser to view the website.
<https://www.MycophenolateREMS.com>

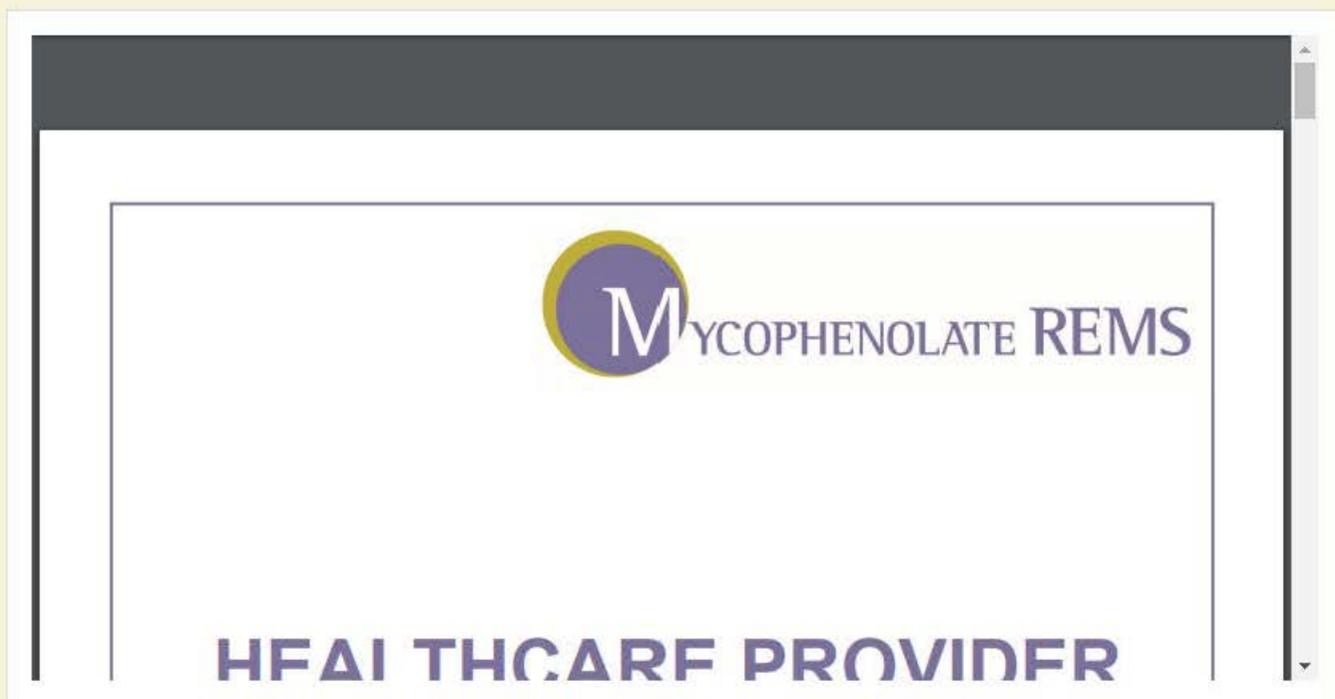
This information is used only for the purpose of sending this email. See full [Privacy Statement](#).

Prescriber Documentation of Training

Accessed from Prescriber Training button on Prescriber Overview Page

PRESCRIBER TRAINING

View the Healthcare Provider Brochure



Document Your Training

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

Email :

Re-type Email :

[Continue >>](#)

[Cancel](#)

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 mycophenolate mofetil
- Generic mycophenolic acid

As a prescriber of mycophenolate to female patients of reproductive potential,* I understand that I complete this Training Confirmation Form to document my training in the Mycophenolate REMS. This training could include reading the *Prescribing Information* and the *Healthcare Provider Brochure* or attending an accredited continuing education (CE) training program. As part of the REMS, the manufacturers of mycophenolate products have provided independent commercially-supported educational grants to support CME/CE activities regarding risks associated with mycophenolate use during pregnancy. A full list of CME/CE providers can be found on www.MycophenolateREMS.com.

*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 have agreed to do the following:

1. Read and understand the *Prescribing Information* for mycophenolate and the *Healthcare Provider Brochure*. Consider enrolling in an accredited CME/CE activity to further understand your role in the treatment of patients taking mycophenolate products. A full list of CME/CE providers can be found on www.MycophenolateREMS.com.
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 *Patient Information 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 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 *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.

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 Prescriber Training Confirmation Form I attest to follow the Mycophenolate REMS requirements outlined above.

PRESCRIBER ACCOUNT

Prescriber Information

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 :	<input type="text"/>
First Name* :	<input type="text"/>
Last Name* :	<input type="text"/>
Address1* :	<input type="text"/>
Address2 :	<input type="text"/>
City* :	<input type="text"/>
State* :	<input type="text" value="▼"/>
ZIP* :	<input type="text"/>
Phone* :	(<input type="text"/>) <input type="text"/> - <input type="text"/>
FAX :	(<input type="text"/>) <input type="text"/> - <input type="text"/>
NPI Number* :	<input type="text"/>
Degree* :	<input type="text" value="▼"/>
Specialty* :	<input type="text" value="▼"/>

Complete Your Registration

Set your password.

Username is your email address : lonnie.dee@abc.com

Password : ?

Confirm Password :



Welcome John Smith
[Edit My Profile](#) | [Logout](#)

[Prescriber Overview](#) [Patient Overview](#) [Other Healthcare Professionals Overview](#) [REMS Materials](#) [Report a Pregnancy](#) [Additional Resources](#) [FAQs](#) [For CME/CE Community](#)

PRESCRIBER ACCOUNT

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

- You will receive an email confirmation of your current enrollment.
IMPORTANT : Add noreply@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

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

Y
m

Login Credentials

Prescriber Login

Email :

Password :

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

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

- heart
- esophagus
- kidney
- and nervous system

As a prescriber of mycophenolate, you should document your training in the Mycophenolate REMS by completing a *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:

Prescriber Training

To view the Healthcare Providers Brochure, and document your training, click here.

REMS Materials

Download or Order materials, click here.

DATA INSIGHTS

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

Forgot Password

Accessed from Prescriber Login Screen as a link

[Prescriber
Overview](#)

[Patient
Overview](#)

[Other Healthcare
Professionals Overview](#)

[REMS
Materials](#)

[Report a
Pregnancy](#)

[Additional
Resources](#)

[FAQs](#)

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
m

Login Credentials

Forgot Password

Email :

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

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

- the distal limbs
- heart
- esophagus
- kidney

Prescriber Training
To view the Healthcare Providers Brochure, and document your training, click here.

REMS Materials
Download or Order materials, click here.

DATA INSIGHTS

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

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 REMS materials:

1. **ONLINE** – You can order the materials online. [To Order Online, click here](#)
2. **BY PHONE** – You can order materials by calling the Mycophenolate REMS call center at 1-800-617-3191.
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 REMS Materials:



Login Credentials
✕

You must login or create an account to order program materials. Please login or click to create an account below.

Prescriber Login

Email :

Password :

[Create an Account](#)

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



Healthcare Provider 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](#)



Dear Healthcare Provider (DHCP) Letter

- For prescribers

PRESCRIBER ACCOUNT

Prescriber Information

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 :	<input type="text"/>
First Name* :	<input type="text"/>
Last Name* :	<input type="text"/>
Address1* :	<input type="text"/>
Address2 :	<input type="text"/>
City* :	<input type="text"/>
State* :	<input type="text" value="▼"/>
ZIP* :	<input type="text"/>
Phone* :	(<input type="text"/>) <input type="text"/> - <input type="text"/>
FAX :	(<input type="text"/>) <input type="text"/> - <input type="text"/>
NPI Number* :	<input type="text"/>
Degree* :	<input type="text" value="▼"/>
Specialty* :	<input type="text" value="▼"/>

Complete Your Registration

Set your password.

Username is your email address : lonnie.dee@abc.com

Password : ?

Confirm Password :



Welcome John Smith

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

[Prescriber Overview](#)

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[Other Healthcare Professionals Overview](#)

[REMS Materials](#)

[Report a Pregnancy](#)

[Additional Resources](#)

[FAQs](#)

[For CME/CE Community](#)

PRESCRIBER ACCOUNT

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

- You will receive an email confirmation of your current enrollment.
IMPORTANT : Add noreply@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

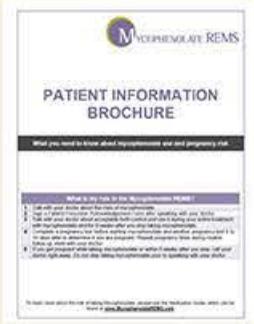
Order Program Materials

ORDER MATERIALS

Step 1 of 4: Select Materials

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

Your REMS Materials:



Patient Information Brochure: What You Need To Know About Mycophenolate

Qty: ▼

- 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



Healthcare Provider Brochure

Qty: ▼

- 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: ▼

- For prescribers to give to female patients of reproductive potential



Prescriber Training Confirmation Form

Qty: ▼

- 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.



Welcome John Smith

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

[Prescriber Overview](#)

[Patient Overview](#)

[Other Healthcare Professionals Overview](#)

[REMS Materials](#)

[Report a Pregnancy](#)

[Additional Resources](#)

[FAQs](#)

[For CME/CE Community](#)

ORDER MATERIALS

Step 2 of 4: Select Shipping Address

Please select a shipping address.

- Attn:
100 Main St
Philadelphia, PA 99999
- Attn:
123 Main St
Blue Bell, PA 32823
- 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	Patient Information Brochure: What You Need To Know About Mycophenolate

Shipping Information
Shipping Address : Attn: John Smith 100 Main St Philadelphia, PA 99999
Contact Information : Phone : (555) 453-5345



Welcome John Smith

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[Other Healthcare Professionals Overview](#)

[REMS Materials](#)

[Report a Pregnancy](#)

[Additional Resources](#)

[FAQs](#)

[For CME/CE Community](#)

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)

- [Prescriber Overview](#)
- [Patient Overview](#)
- [Other Healthcare Professionals Overview](#)
- [REMS Materials](#)
- [Report a Pregnancy](#)
- [Additional Resources](#)
- [FAQs](#)
- [For CME/CE Community](#)

VIEW AND EDIT MY PROFILE

▲ Professional Information Hide Details...

NPI Number : 1003000100 [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](#)

▲ Other Information Hide Details...

Email : Lonnie.Dee@abc.com [Edit](#)
 Password : ***** [Edit](#)

▲ Addresses Hide Details...

Primary Address	Secondary Address
Institution : Attn First Name : John Attn Last Name : Smith Address1 : 100 Main St Address2 : City : Philadelphia State : PA ZIP : 99999 Phone : (555) 453-5345 FAX :	Institution : Attn First Name : John Attn Last Name : Smith Address1 : 123 Main St Address2 : City : Blue Bell State : PA ZIP : 32823 Phone : (423) 473-9883 FAX :
Edit	Edit Delete

Mycophenolate REMS Website Screenshots

MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS
AND CONGENITAL DEFECTS

[Prescriber
Overview](#)

[Patient
Overview](#)

[FAQs](#)

WELCOME

What is the Mycophenolate REMS?

The Mycophenolate REMS is designed to help reduce the risk of miscarriage and birth defects associated with the use of mycophenolate during pregnancy. It is a risk reduction strategy.

What are the risks of mycophenolate during pregnancy?

- Higher risk of miscarriage
- Higher risk that the baby will have birth defects.

Who should be informed about the Mycophenolate REMS?

Prescribers

For Prescriber Overview,
[click here](#)

Patients

For Patient Overview,
[click here](#)

Other Healthcare Professionals

For Other Healthcare
Professionals, [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:

- Educating healthcare providers on the following:
 - The increased risks of miscarriage and birth defects 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.
- Informing females of reproductive potential who are prescribed mycophenolate about:
 - The increased risks of pregnancy loss (miscarriage) and birth defects
 - The importance of pregnancy prevention and planning when taking mycophenolate

What medications contain mycophenolate?

Mycophenolate Mofetil
CellCept® by Cellego USA, Inc.

Mycophenolic Acid
Myfortic® by Novartis Pharmaceuticals



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 increased 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?

Prescribers For Prescriber Overview, click here	Patients For Patient Overview, click here	Other Healthcare Professionals For Other Healthcare Professionals, 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 miscarriage and birth defects 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 pregnancy loss (miscarriage) and birth defects.
 - 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 ovaries 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

You should become familiar with the increased 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 *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/email it to:

Mycophenolate REMS
200 Pinecrest Plaza
Morgantown, WV 26505-8065
support@mycophenolateREMS.com

- Call 1-800-617-8191

Step 2 - Educate Females of Reproductive Potential

Step 3 - Check Pregnancy Status

Step 4 - Report any pregnancies to the Mycophenolate Pregnancy Registry

Prescriber Training

To view the Healthcare Provider Brochure, and document your training, [click here](#).

REMS Materials

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

DATA INSIGHTS

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†:

- 25 had spontaneous abortions
- 14 had a malformed fetus or infant, of which six had ear abnormalities

While available data are limited, structural malformations occur in approximately 20% of live-born infants exposed in utero to mycophenolate. First trimester pregnancy loss rates have been reported to be approximately 45%†.

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

Healthcare providers are not required to complete the *Prescriber Training Confirmation Form* in order to prescribe mycophenolate-containing medicines. However, healthcare providers who prescribe mycophenolate-containing medicines will be contacted by the Mycophenolate REMS and encouraged to become trained. This training could include reading the *Prescribing Information* and the *Healthcare Provider Brochure*.

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 REMS materials:

1. ONLINE – You can order the materials online. [To Order Online, click here](#)
2. BY PHONE – 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 REMS Materials:



Patient Information 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

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



Healthcare Provider 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](#)



Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

[View to Print or Save](#)



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](#)



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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



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](#)



CellCept Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

[View to Print or Save](#)

Generic Medication Guides

Drug Name	Generic Name	Company	Links

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

*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.



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 increased risks of mycophenolate exposure during pregnancy. Discuss the increased risks of miscarriage and birth defects 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 *Patient Information Brochure: What You Need To Know About Mycophenolate*.

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

Patients need to understand:

- the increased risks of miscarriage and birth defects while using mycophenolate
- their birth control options
- their role in the Mycophenolate REMS

- 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-conceptional 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](#)

ACCEPTABLE BIRTH CONTROL OPTIONS

Guide your patients to choose from the following birth control options for use during treatment with mycophenolate:

<p>Option 1 Use Method Alone</p> <ul style="list-style-type: none"> Pick one item from (A) Most effective: Less than 1 pregnancy per 100 women in one year 	<p>A</p>
<p>Option 2 Use Hormone & Barrier</p> <ul style="list-style-type: none"> Pick one item from (B) and one item from (C1) or (C2) shown below 4-7 pregnancies per 100 women in one year 	<p>B</p>
<p>Option 3 Use Two Barriers</p> <ul style="list-style-type: none"> Pick one item from (C1) and one from (C2) Least effective: 13 or more pregnancies per 100 women in one year 	<p>C</p>

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. For complete details regarding acceptable birth control options, please see Prescribing Information, including Section 10.0 (2) and the Medication Guide, which can be found at [MycophenolateREMS.com](#)

* Females of reproductive potential includes girls who have entered puberty and all women who have a uterus and ovaries 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.

Step 3 - Check Pregnancy Status

Step 4 - 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 providers are not required to complete the *Prescriber Training Confirmation Form* in order to prescribe mycophenolate-containing medicines. However, healthcare providers who prescribe mycophenolate-containing medicines will be contacted by the Mycophenolate REMS and encouraged to become trained. This training could include reading the *Prescribing Information* and the *Healthcare Provider Brochure*.

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 REMS materials:

- ONLINE** – You can order the materials online. [To Order Online, click here](#)
- BY PHONE** – You can order materials by calling the Mycophenolate REMS call center at 1-800-617-8191.
- 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 REMS Materials:



Patient Information 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

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



Healthcare Provider 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](#)



Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

[View to Print or Save](#)



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

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CellCept Medication Guide

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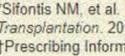
Generic Medication Guides

Drug Name	Generic Name	Company	Links

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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 - 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 increased 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 increased risks to the fetus.

Step 4 - Report any pregnancies to the Mycophenolate Pregnancy Registry

Prescriber Training

To view the Healthcare Provider Brochure, and document your training, [click here.](#)

REMS Materials

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DATA INSIGHTS

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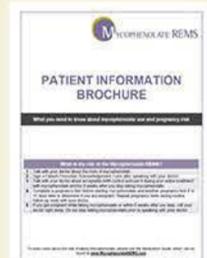
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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

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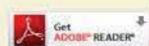
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INFORMATION FOR PRESCRIBERS

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 - Check Pregnancy Status**
- ➔ **Step 4 - 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 become 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
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 and encourage patients to read the [Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients](#) on this website**

Prescriber Training

To view the Healthcare Provider Brochure, and document your training, [click here](#).

REMS Materials

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DATA INSIGHTS

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While available data are limited, structural malformations occur in approximately 20% of live-born infants exposed in utero to mycophenolate. First trimester pregnancy loss rates have been reported to be approximately 45%*†.

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

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Patient Overview Page

Accessed from Main menu links or Patients button on Home Page

INFORMATION FOR PATIENTS

I take mycophenolate, what do I need to know and do? *Click an item below to expand details.*

Understanding the increased 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 increased risks of mycophenolate during pregnancy.

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

- Higher risk of 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 *Patient Information 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?

Report a Pregnancy

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

REMS Materials

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

DATA INSIGHTS

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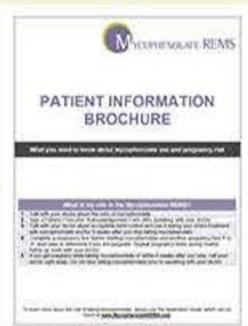
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Program Resources and Educational Materials

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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 expand details.*

Understanding the increased 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 BIRTH CONTROL OPTIONS

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

Option 1 Use Method Alone Pick one item from (A) ▶ Most effective: Less than 1 pregnancy per 100 women in one year	A 
Option 2 Use Hormone & Barrier Pick one item from (B) and one item from (C1) or (C2) shown below ▶ 4-7 pregnancies per 100 women in one year	B 
Option 3 Use Two Barriers Pick one item from (C1) and one from (C2) ▶ Least effective: 13 or more pregnancies per 100 women in one year	C 

To learn more about all the risks of taking mycophenolate, please see the Medication guide, which can be found at MycophenolateREMS.com

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](#).

REMS Materials

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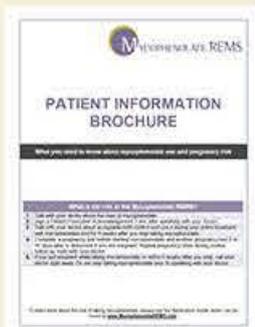
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While available data are limited, structural malformations occur in approximately 20% of live-born infants exposed in utero to mycophenolate. First trimester pregnancy loss rates have been reported to be approximately 45%*†.

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INFORMATION FOR PATIENTS

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Understanding the increased 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

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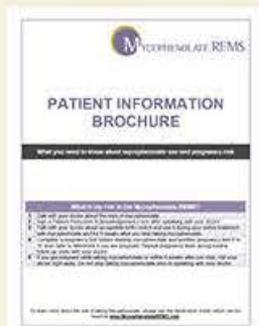
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- ⊕ Understanding the increased risks of taking mycophenolate during pregnancy
- ⊕ Do I need to use birth control?
- ⊕ Do I need a pregnancy test?
- ⊖ What if I am thinking about getting pregnant?
 If you are thinking about having a baby, talk with 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
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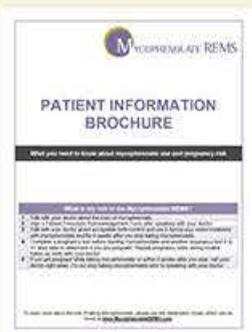
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- Do I need a pregnancy test?
- What if I am thinking about getting pregnant?
- What if I get pregnant?

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](#)

Report a Pregnancy

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

REMS Materials

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

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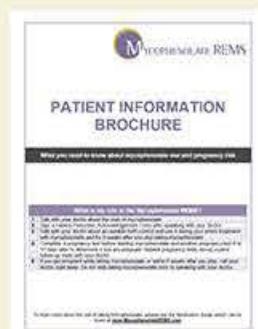
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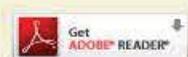
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Other Healthcare Professionals Overview Page

Accessed from Main menu links or Other Healthcare Professionals Overview
button on Home Page

INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS? [Click step to expand details.](#)

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

You should become familiar with the increased 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

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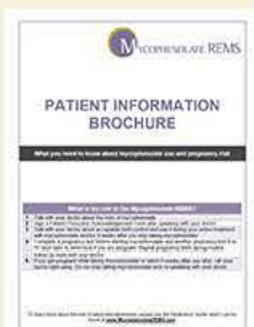
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Program Resources and Educational Materials

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 REMS Materials:



Patient Information 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

[View to Print or Save](#)



Healthcare Provider Brochure

- For prescribers

[View to Print or Save](#)



CellCept Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

[View to Print or Save](#)

Generic Medication Guides

Drug Name	Generic Name	Company	Links

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

*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.



INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS? [Click step to expand details.](#)

Step 1 - Understand the Increased 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 in women taking mycophenolate.

Discuss the following with females of reproductive potential:

- The increased risks of miscarriage and birth defects 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 BIRTH CONTROL OPTIONS

Guide your patients to choose from the following birth control options for use during treatment with mycophenolate:

Option 1 Use Method Alone Pick one item from (A) ▶ Most effective: Less than 1 pregnancy per 100 women in one year	A Intrauterine Device (IUD) Tubal Sterilization Vasectomy
Option 2 Use Hormone & Barrier Pick one item from (B) and one item from (C1) or (C2) shown below ▶ 4-7 pregnancies per 100 women in one year	B Progesterone Only Injection Birth Control Pill Birth Control (Progesterone) Patch Vaginal Ring Progesterone Only Implant
Option 3 Use Two Barriers Pick one item from (C1) and one from (C2) ▶ Least effective: 13 or more pregnancies per 100 women in one year	C 1 Female Condom Male Condom 2 Female Diaphragm with Spermicide Female Birth Control Sponge Cervical Cap with Spermicide

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. For complete safety information, please see Prescribing Information, including Revised WARNING and Medication Guide, which can be found at [MycophenolateREMS.com](#)

* Females of reproductive potential includes girls who have entered puberty and all women who have a uterus and ovaries 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.

Step 3 - Report Pregnancies

DATA INSIGHTS

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†:

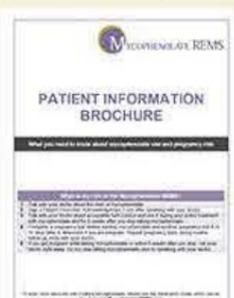
- 25 had spontaneous abortions
- 14 had a malformed fetus or infant, of which six had ear abnormalities

While available data are limited, structural malformations occur in approximately 20% of live-born infants exposed in utero to mycophenolate. First trimester pregnancy loss rates have been reported to be approximately 45%*†.

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[View to Print or Save](#)



Healthcare Provider Brochure

- For prescribers

[View to Print or Save](#)



CellCept Medication Guide

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Myfortic Medication Guide

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INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS? [Click step to expand details.](#)

➔ **Step 1 - Understand the Increased 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.

[Report a Pregnancy](#)

DATA INSIGHTS

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:

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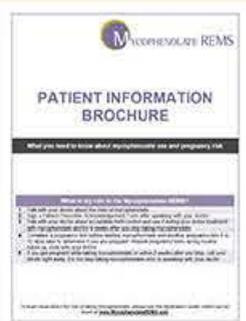
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Healthcare Provider Brochure

- For prescribers

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CellCept Medication Guide

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Generic Medication Guides

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†Prescribing Information for mycophenolate.



REMS Materials

Accessed from Main menu link on Home Page



MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS
AND CONGENITAL MALFORMATIONS

[Prescriber
Overview](#)

[Patient
Overview](#)

[Other Healthcare
Professionals Overview](#)

[REMS
Materials](#)

[Report a
Pregnancy](#)

[Additional
Resources](#)

[FAQs](#)

- [Prescribers](#)
- [Patients](#)
- [Other Healthcare Professionals](#)



Prescribers

Resources and Educational Materials for Prescribers

Your REMS Materials:



Patient Information 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

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



Healthcare Provider 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](#)



Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

[View to Print or Save](#)



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](#)



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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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](#)



CellCept Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

[View to Print or Save](#)

Generic Medication Guides

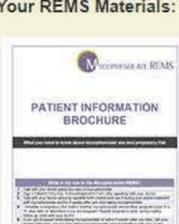
Drug Name	Generic Name	Company	Links

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

Patients

Resources and Educational Materials for Patients

Your REMS Materials:



Patient Information 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

[View to Print or Save](#)



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

[View to Print or Save](#)

Other Healthcare Professionals

Resources and Educational Materials for Other Healthcare Professionals

Your REMS Materials:



Patient Information 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

[View to Print or Save](#)



Healthcare Provider 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](#)



CellCept Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

[View to Print or Save](#)

Generic Medication Guides

Drug Name	Generic Name	Company	Links

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Report a Pregnancy Page

[Prescriber Overview](#)[Patient Overview](#)[Other Healthcare Professionals Overview](#)[REMS Materials](#)[Report a Pregnancy](#)[Additional Resources](#)[FAQs](#)

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.

Patients

I am a pregnant patient, please contact me.

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 below.
- **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.

Healthcare Professionals

I am a healthcare professional, please contact me.

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.

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.

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.

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.

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 below.
- **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.

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

There are 2 ways to report a pregnancy to the Mycophenolate Pregnancy Registry:

1. **BY PHONE** - You can call 1-800-617-8191.
2. **ONLINE** - You can provide information to the Mycophenolate Pregnancy Registry. See the "Report a Pregnancy" button on this page to contact you to confirm information.

What should be reported to the Mycophenolate Pregnancy Registry?

Any pregnancy, planned or unplanned, that occurs:

- While taking mycophenolate
- Within 6 weeks after stopping treatment

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.

Patients

I am a pregnant patient, please contact me.

Healthcare Professionals

I am a healthcare professional, please contact me.

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



Report a Pregnancy



Please provide the contact information requested below. Required fields are indicated by an asterisk (*)

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.

Patient Contact Information

First Name* :

Last Name* :

Address 1* :

Address 2 :

City* :

State* :

ZIP* :

Email Address :

Primary Phone Number* :

Secondary Phone Number :

Fax Number :

Preferred Contact Method* :

Healthcare Provider Contact Information

First Name :

Last Name :

Address 1 :

Address 2 :

City :

State :

ZIP :

Email Address :

Primary Phone Number :

Secondary Phone Number :

Fax Number :

Preferred Contact Method :

[Patient FAQs](#)

[Prescriber FAQs](#)

I have more questions, where can I get answers?

You can:

Reference ID: 4732128

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

Report a Pregnancy Page

HCP Not Logged In

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 below
- **Patients** - Tell your doctor or pharmacist. Your doctor or pharmacist will report to the Registry.

How do I report a pregnancy?

There are 2 ways to report a pregnancy:

1. **BY PHONE** - You can call 1-800-368-7777
2. **ONLINE** - You can pre-register on the Mycophenolate Pregnancy Registry. See the "How to Register" page for more information. We will contact you to confirm the pregnancy.

What should be reported?

Any pregnancy, planned or unplanned, should be reported.

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

Healthcare Professionals

I am a healthcare professional, please contact me.

Login Credentials



You are not currently logged on. If you log on, profile information is passed on to the pregnancy registry. [Continue without logging in.](#)

Prescriber Login

Email :

Password :

Login

Cancel

[Forgot Password](#)

[Privacy Statement](#)



[Prescriber Overview](#)

[Patient Overview](#)

[Other Healthcare Professionals Overview](#)

[REMS Materials](#)

[Report a Pregnancy](#)

[Additional Resources](#)

[FAQs](#)

MYCOPHENOLATE PREGNANCY REGISTRY

Report a Pregnancy



Please provide the contact information requested below. Required fields are indicated by an asterisk (*)

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.

Healthcare Provider Contact Information

First Name* :

Last Name* :

Address 1* :

Address 2 :

City* :

State* :

ZIP* :

Email Address :

Primary Phone Number* :

Secondary Phone Number :

Fax Number :

Preferred Contact Method* :

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](#)

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

- Planned Parenthood:*
www.plannedparenthood.org
- Food and Drug Administration:
www.fda.gov/consumers/free-publications-women/birth-control

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 *Patient Information Brochure: What You Need To Know About Mycophenolate* brochure. This brochure is available from your doctor or can be viewed on this website.

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 *Patient Information Brochure: What You Need To Know About Mycophenolate* brochure. This brochure is available from your doctor and can also be viewed on this website.

- 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 website.

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?

You can also contact Planned Parenthood at 1-800-230-PLAN (1-800-230-7526), online at www.plannedparenthood.org or text "PPNOW" to 774636 (PPINFO) to get answers (standard message and data rates may apply).

- 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 mycophenolate mofetil
- Generic mycophenolic acid

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

- 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 disabling 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?

- *Patient Information 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 Pregnancy Registry Frequently Asked Questions for Patients*
Provides answers to frequently asked questions about the Registry.

• Prescribers

- Who is the 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 and encourage patients to read the *Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients* on this website

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 applicants of Mycophenolate REMS and/or submitted for publication in peer-reviewed scientific journals.

- Do I still report pregnancies to the National Transplantation Pregnancy Registry (NTPR)?

All pregnancies occurring during treatment with mycophenolate or within 6 weeks following discontinuation of treatment should be reported to the Mycophenolate Pregnancy Registry, regardless of indication, for inclusion and follow-up. In addition to reporting exposed pregnancies to the Mycophenolate Pregnancy Registry, you may also report pregnancies to the NTPR.

- How can I obtain more information?

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

- 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

▪ 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.

- 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.

▪ 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



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[Report a Pregnancy](#)

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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 [Mycophenolate REMS](https://www.MycophenolateREMS.com) on the [MycophenolateREMS.com](https://www.MycophenolateREMS.com) website. Please copy and paste the link into your browser to view the website.
<https://www.MycophenolateREMS.com>

This information is used only for the purpose of sending this email. See full [Privacy Statement](#)

Prescriber Documentation of Training

Accessed from Prescriber Training button on Prescriber Overview Page

PRESCRIBER TRAINING

View the Healthcare Provider Brochure



Document Your 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 mycophenolate mofetil
- Generic mycophenolic acid

As a prescriber of mycophenolate to female patients of reproductive potential,* I understand that I complete this 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 have agreed to do the following:

1. Read and understand the *Prescribing Information* for mycophenolate and the *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 *Patient Information 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 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 *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.

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 Prescriber Training Confirmation Form I attest to follow the Mycophenolate REMS requirements outlined above.

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[Continue >>](#)

[Cancel](#)

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PRESCRIBER ACCOUNT

Prescriber Information

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 :	<input type="text"/>
First Name* :	<input type="text"/>
Last Name* :	<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"/>	
NPI Number* :	<input type="text"/>
Degree* :	<input type="text"/>
Specialty* :	<input type="text"/>

Complete Your Registration

Set your password.

Username is your email address : lonnie.dee@abc.com

Password : ?

Confirm Password :



Welcome **John Smith**

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

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PRESCRIBER ACCOUNT

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

- You will receive an email confirmation of your current enrollment.

IMPORTANT : Add noreply@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



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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

You
m

Login Credentials ✕

Prescriber Login

Email :

Password :

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

Prescriber Training
To view the Healthcare Providers Brochure, and document your training, click here.

REMS Materials
Download or Order materials, click here.

Forgot Password

Accessed from Prescriber Login Screen as a link

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[REMS Materials](#)

[Report a Pregnancy](#)

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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

Login Credentials ✕

Forgot Password

Email :

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

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

Prescriber Training
To view the Healthcare Providers Brochure, and document your training, click here.

REMS Materials
Download or Order materials, click here.

DATA INSIGHTS

- the distal limbs
- heart
- esophagus
- kidney

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

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 REMS materials:

1. **ONLINE** – You can order the materials online. [To Order Online, click here](#)
2. **BY PHONE** – You can order materials by calling the Mycophenolate REMS call center at 1-800-617-3191.
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 REMS Materials:



Login Credentials
✕

You must login or create an account to order program materials. Please login or click to create an account below.

Prescriber Login

Email :

Password :

[Create an Account](#)

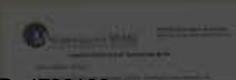
[Forgot Password](#)
[Privacy Statement](#)



Healthcare Provider 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](#)



Dear Healthcare Provider (DHCP) Letter

- For prescribers

PRESCRIBER ACCOUNT

Prescriber Information

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 :	<input type="text"/>
First Name* :	<input type="text"/>
Last Name* :	<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"/>	
NPI Number* :	<input type="text"/>
Degree* :	<input type="text"/>
Specialty* :	<input type="text"/>

Complete Your Registration

Set your password.

Username is your email address : lonnie.dee@abc.com

Password : ?

Confirm Password :



Welcome John Smith

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PRESCRIBER ACCOUNT

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

- You will receive an email confirmation of your current enrollment.

IMPORTANT : Add noreply@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

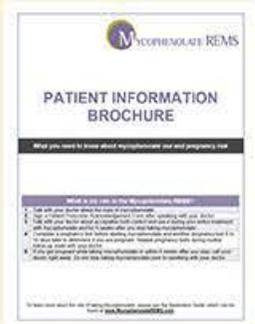
Order Program Materials

ORDER MATERIALS

Step 1 of 4: Select Materials

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

Your REMS Materials:



Patient Information 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



Healthcare Provider 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



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](#)

ORDER MATERIALS

Step 2 of 4: Select Shipping Address

Please select a shipping address.

- Attn:
100 Main St
Philadelphia, PA 99999
- Attn:
123 Main St
Blue Bell, PA 32823
- 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	Patient Information Brochure: What You Need To Know About Mycophenolate

Shipping Information
Shipping Address : Attn: John Smith 100 Main St Philadelphia, PA 99999
Contact Information : Phone : (555) 453-5345

[<< Back](#) [Submit Order](#) [Cancel](#)



MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS
AND CONGENITAL MALFORMATIONS

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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)

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VIEW AND EDIT MY PROFILE

Professional Information Hide Details...

NPI Number : 1003000100

[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](#)

Other Information Hide Details...

Email : Lonnie.Dee@abc.com

[Edit](#)

Password : *****

[Edit](#)

Addresses Hide Details...

Primary Address

Institution :

Attn First Name : John

Attn Last Name : Smith

Address1 : 100 Main St

Address2 :

City : Philadelphia

State : PA

ZIP : 99999

Phone : (555) 453-5345

FAX :

[Edit](#)

Secondary Address

Institution :

Attn First Name : John

Attn Last Name : Smith

Address1 : 123 Main St

Address2 :

City : Blue Bell

State : PA

ZIP : 32823

Phone : (423) 473-9883

FAX :

[Edit](#) [Delete](#)



IMPORTANT DRUG WARNING
Regarding Mycophenolate-Containing Products

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, 2014 and 2017 REMS Assessment surveys of female patients taking mycophenolate during reproductive age indicated that **many patients do NOT understand these risks.**

Discuss the following with your female patients of reproductive potential:

- The **increased risks** of miscarriage and birth defects 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.
- **Report pregnancies** to the Mycophenolate Pregnancy Registry, 1-800- 617-8191, or online at www.mycophenolatepregnancyregistry.com, or www.MycophenolateREMS.com.

A training tool is available for patients:

- **Patient Information Brochure: What You Need to Know About Mycophenolate.**
This brochure discusses the risks of miscarriage, birth defects, birth control options and information on the Mycophenolate REMS.

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

*The Mycophenolate REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to inform healthcare providers and patients about the risks of taking mycophenolate during pregnancy.

Training Tools		Web Link Or How To Order
	<p>Patient Information Brochure: What You Need To Know About Mycophenolate</p>	<p>https://www.mycophenolate-rems.com/Docs/PatientResourceKit.pdf</p>
	<p>Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients</p>	<p>https://www.mycophenolate-rems.com/Docs/PatientRegistryFAQ.pdf</p>
	<p>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>



IMPORTANT DRUG WARNING
Regarding Mycophenolate-Containing Products

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, 2014 and 2017 REMS Assessment surveys of female patients taking mycophenolate during reproductive age indicated that **many patients do NOT understand these risks.**

Discuss the following with your female patients of reproductive potential:

- The **increased risks** of miscarriage and birth defects 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.
- **Report pregnancies** to the Mycophenolate Pregnancy Registry, 1-800- 617-8191, or online at www.mycophenolatepregnancyregistry.com, or www.MycophenolateREMS.com.

A training tool is available for patients:

- **Patient Information Brochure: What You Need to Know About Mycophenolate.** This brochure discusses the risks of miscarriage, birth defects, birth control options and information on the Mycophenolate REMS.

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.**

REMS-compliant accredited, independent Continuing Education (CE) is available for healthcare providers who prescribe and/or participate in the treatment of patients taking mycophenolate products.

- Please visit www.MycophenolateREMS.com or call 1-800-617-8191 for additional information on Continuing Education (CE).

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

*The Mycophenolate REMS(Risk Evaluation and Mitigation Strategy) is a program required by the FDA to inform healthcare providers and patients about the risks of taking mycophenolate during pregnancy.

Training Tools		Web Link Or How To Order
	<p>Patient Information Brochure: What You Need To Know About Mycophenolate</p>	<p>https://www.mycophenolate-rems.com/Docs/PatientResourceKit.pdf</p>
	<p>Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients</p>	<p>https://www.mycophenolate-rems.com/Docs/PatientRegistryFAQ.pdf</p>
	<p>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>



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.

Surveys of female patients taking mycophenolate during reproductive age indicated that **many patients do NOT understand these risks.**

Discuss the following with female patients of reproductive potential:

- The **increased risks** of miscarriage and birth defects 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.

The Mycophenolate Pregnancy Registry has been established to evaluate mycophenolate-exposed pregnancies and their outcomes. Consider sharing with patients the **Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients**, which is available on www.MycophenolateREMS.com.

- **Report pregnancies to the Mycophenolate Pregnancy Registry, 1-800-617- 8191, or online at www.mycophenolatepregnancyregistry.com, or www.MycophenolateREMS.com.**

Provide patients the Patient Information Brochure: What You Need to Know About Mycophenolate. This brochure discusses the risks of miscarriage, birth defects, birth control options, and the Mycophenolate REMS.

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 female patients of reproductive potential understand the risks and benefits associated with mycophenolate treatment.

Sincerely,
Mycophenolate REMS Team

*The Mycophenolate REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to inform healthcare providers and patients about the risks of taking mycophenolate during pregnancy.

Training Tools		Web Link Or How To Order
	<p>Patient Information Brochure: What You Need To Know About Mycophenolate</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientResourceKit.pdf</p>
	<p>Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientRegistryFAQ.pdf</p>
	<p>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>



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.

Surveys of female patients taking mycophenolate during reproductive age indicated that **many patients do NOT understand these risks.**

Discuss the following with female patients of reproductive potential:

- The **increased risks** of miscarriage and birth defects 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.

The Mycophenolate Pregnancy Registry has been established to evaluate mycophenolate-exposed pregnancies and their outcomes. Consider sharing with patients the **Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients**, which is available on www.MycophenolateREMS.com.

- **Report pregnancies to the Mycophenolate Pregnancy Registry, 1-800-617- 8191, or online at www.mycophenolatepregnancyregistry.com, or www.MycophenolateREMS.com.**

Provide patients the Patient Information Brochure: What You Need to Know About Mycophenolate. This brochure discusses the risks of miscarriage, birth defects, birth control options, and the Mycophenolate REMS.

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**.

REMS-compliant accredited, independent Continuing Education (CE) is available for healthcare providers who prescribe and/or participate in the treatment of patients taking mycophenolate products.

- Please visit www.MycophenolateREMS.com or call 1-800-617-8191 for additional information on Continuing Education (CE).

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

*The Mycophenolate REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to inform healthcare providers and patients about the risks of taking mycophenolate during pregnancy.

Training Tools		Web Link Or How To Order
	<p>Patient Information Brochure: What You Need To Know About Mycophenolate</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientResourceKit.pdf</p>
	<p>Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients</p>	<p>https://www.mycophenolate.rems.com/Docs/PatientRegistryFAQ.pdf</p>
	<p>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>

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. This training could include reading the *Prescribing Information* and the *Healthcare Provider Brochure* or attending an accredited continuing education (CE) training program. As part of the REMS, the manufacturers of mycophenolate products have provided independent commercially-supported educational grants to support CME/CE activities regarding risks associated with mycophenolate use during pregnancy. A full list of CME/CE providers can be found on www.MycophenolateREMS.com.

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

I have agreed to do the following:

1. Read and understand the *Prescribing Information* for mycophenolate and the *Healthcare Provider Brochure*. Consider enrolling in an accredited CME/CE activity to further understand your role in the treatment of patients taking mycophenolate products. A full list of CME/CE providers can be found on www.MycophenolateREMS.com.
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 *Patient Information 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 *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.

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 *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, via email to support@mycophenolateREMS.com, or mail it to:

Mycophenolate REMS
200 Pinecrest Plaza, Morgantown, WV 26505-8065

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 Medicine_____	4
Gastroenterology_____	5
Hepatology_____	6
Internal Medicine_____	7
Nephrology_____	8
Neurology_____	9
OB/GYN_____	10
Pediatrics_____	11
Pulmonology_____	12
Rheumatology_____	13
Surgery_____	14
Transplantation_____	15
Other_____	16
N/A_____	17

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:

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- 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.

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

I have agreed to do the following:

1. Read and understand the *Prescribing Information* for mycophenolate and the *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 *Patient Information 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 *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.

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 *Prescriber Training Confirmation Form* by visiting www.MycophenolateREMS.com and completing the online form.

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Mycophenolate REMS
200 Pinecrest Plaza, Morgantown, WV 26505-8065

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Specialty	Specialty Code
Allergy and Immunology	1
Cardiology	2
Dermatology	3
Family Medicine	4
Gastroenterology	5
Hepatology	6
Internal Medicine	7
Nephrology	8
Neurology	9
OB/GYN	10
Pediatrics	11
Pulmonology	12
Rheumatology	13
Surgery	14
Transplantation	15
Other	16
N/A	17

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*, (Center Name) will complete and return this training confirmation form to document training in the Mycophenolate REMS. This training could include reading the *Prescribing Information* and the *Healthcare Provider Brochure* or attending an accredited continuing education (CME/CE) training program. As part of the REMS, the manufacturers of mycophenolate products have provided independent commercially-supported educational grants to support CME/CE activities regarding risks associated with mycophenolate use during pregnancy. A full list of CME/CE providers can be found on www.MycophenolateREMS.com.

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

This Center agrees to do the following:

1. Read and understand the *Prescribing Information* for mycophenolate and the *Healthcare Provider Brochure*. Consider enrolling in an accredited CME/CE activity to further understand your role in the treatment of patients taking mycophenolate products. A full list of CME/CE providers can be found on www.MycophenolateREMS.com.
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 *Patient Information 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 *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. Describe how your center plans to implement the Mycophenolate REMS requirements (please explain/outline process below):



MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS AND CONGENITAL MALFORMATIONS

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)

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 completed *Center Training Confirmation Form* via fax to 1-800-617-5768, via email to support@mycophenolateREMS.com, or mail it to:

Mycophenolate REMS
200 Pinecrest Place
Morgantown, WV 26505-8065

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 Medicine	4
Gastroenterology	5
Hepatology	6
Internal Medicine	7
Nephrology	8
Neurology	9
OB/GYN	10
Pediatrics	11
Pulmonology	12
Rheumatology	13
Surgery	14
Transplantation	15
Other	16
N/A	17

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

You can submit a completed *Center Training Confirmation Form* via fax to 1-800-617-5768, via email to support@mycophenolateREMS.com, or mail it to:

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Morgantown, WV 26505-8065

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Rheumatology	13
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Transplantation	15
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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 PREGNANCY REGISTRY FREQUENTLY ASKED QUESTIONS FOR PATIENTS

What is the Mycophenolate Pregnancy Registry?

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

Why should I take part in the Mycophenolate Pregnancy Registry?

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

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

Who can be in the Mycophenolate Pregnancy Registry?

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

These medicines contain mycophenolate:

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

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

(Turn page)

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

There are a few simple steps to take.

1. Tell your doctor if you get pregnant

- The Registry will contact you after speaking with your doctor

2. Complete an *Informed Consent* form

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

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

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

4. Let the Registry know if your contact information changes

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

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

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

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

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

How can I get more information?

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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

OZLEM A BELEN
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