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

What is the Mycophenolate REMS?

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

What are the risks of mycophenolate during pregnancy?

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

Who should be informed about the Mycophenolate REMS?

Report a Pregnancy To Report a Pregnancy, click here	Prescribers For Prescriber Overview, click here	Other Healthcare Professionals For Other Healthcare Professionals, click here	Patients For Patient Overview, click here
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What is the goal of the Mycophenolate REMS? The goal of the Mycophenolate REMS is to mitigate the risk of embryofetal toxicity associated with the use of mycophenolate during pregnancy by:

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

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

What medications contain mycophenolate?

Mycophenolate Mofetil

CellCept® by Genentech USA, Inc.

[Generic formulations by >>](#)

Mycophenolic Acid

Myfortic® by Novartis Pharmaceuticals Corporation.

[Generic formulations by >>](#)

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



Prescriber Overview Page

Accessed from Main menu links or Prescribers button on Home page

INFORMATION FOR PRESCRIBERS

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

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

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

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

Report a Pregnancy

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

Prescriber Training

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

Program Materials

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

Document Your Training

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

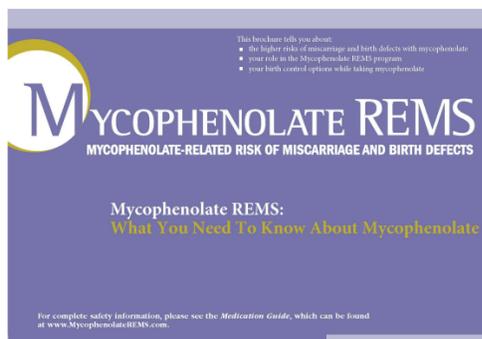
Program Resources and Educational Materials

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

There are three ways to obtain program materials:

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

Your Program Materials:



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

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

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



Mycophenolate REMS Patient-Prescriber Acknowledgment Form

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

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Mycophenolate REMS Healthcare Providers Brochure

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

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Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

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Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter for Centers

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

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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Mycophenolate REMS Prescriber Training Confirmation Form

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

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Mycophenolate REMS OBGYN Referral Letter for Contraceptive Counseling

[View to Print or Save](#)



Mycophenolate REMS OBGYN Referral Letter for Pre-conception Counseling

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CellCept Medication Guide

[View to Print or Save](#)

Generic Mycophenolate Medication Guide

[View to Print or Save](#)



Myfortic Medication Guide

[View to Print or Save](#)

Generic Mycophenolic Acid Medication Guide

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



INFORMATION FOR PRESCRIBERS

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

Step 1 - Document your training in the Mycophenolate REMS

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

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

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

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

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

Mycophenolate REMS
200 Pinecrest Plaza
Morgantown, WV 26505-8065

- Call 1-800-617-8191

Step 2 - Educate Females of Reproductive Potential

Step 3 - Obtain a signed Patient-Prescriber Acknowledgment form

Step 4 - Check Pregnancy Status

Step 5 - Report any pregnancies to the Mycophenolate Pregnancy Registry

Report a Pregnancy

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

Prescriber Training

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Program Materials

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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

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

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

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

Patients need to understand:

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

- **Provide pregnancy planning education.**

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

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

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

Refer patients for pre-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](#)

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

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Acceptable Contraception Methods for Females of Reproductive Potential*

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

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

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

EMERGENCY CONTRACEPTION

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

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

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

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

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

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

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

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

Retain the original copy for your records.

+ **Step 4 - Check Pregnancy Status**

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

 **Report a Pregnancy**

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

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- + Step 3 - Obtain a signed Patient-Prescriber Acknowledgment form**
- Step 4 - Check Pregnancy Status**

You must determine if females of reproductive potential are pregnant:

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

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

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

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

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

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

If you learn that a patient is pregnant:

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

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

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

Report a Pregnancy
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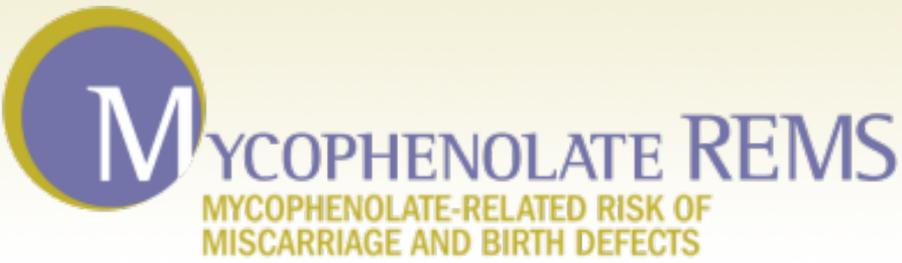
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Patient Overview Page

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

Click an item below to see more information

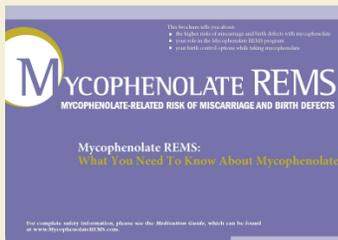
- [+ Understand the risks of taking mycophenolate during pregnancy](#)
- [+ Do I need to use birth control?](#)
- [+ Do I need a pregnancy test?](#)
- [+ What if I am thinking about getting pregnant?](#)
- [+ What if I get pregnant?](#)

Report a Pregnancy
To report a pregnancy, click here.

Program Materials
To view program materials online, click here.

Program Resources and Educational Materials

Your Program Materials:



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

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

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Mycophenolate REMS Patient-Prescriber Acknowledgment

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

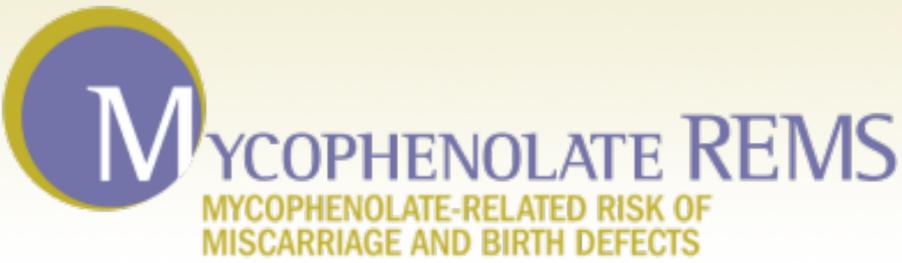
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Click an item below to see more information

Understanding the risks of taking mycophenolate during pregnancy

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

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

Higher risk of losing a pregnancy (miscarriage) during the first 3 months.

- Higher risk that the baby may be born with the birth defects:
 - Defects of the ears
 - Cleft lip or cleft palate
 - Defects of the arms, legs, heart, esophagus, kidney
 - and nervous system

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

Do I need to use birth control?

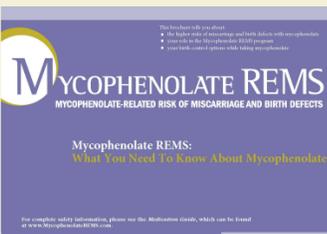
Do I need a pregnancy test?

What if I am thinking about getting pregnant?

What if I get pregnant?

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

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INFORMATION FOR PATIENTS

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Click an item below to see more information

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

You must always use acceptable birth control:

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

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

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

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

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

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

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

- Studies show that mycophenolate lowers blood levels of certain hormones in the **birth control pill**.
- It is possible that birth control pills may not work as well when you take mycophenolate and you could become pregnant.
- It is possible that other hormone methods (like the **patch**, the **ring**, the **shot**, and the **implant**) may also not work well and you could become pregnant.
- It is important that a **barrier method** of birth control is **also used** with any hormone method of birth control.

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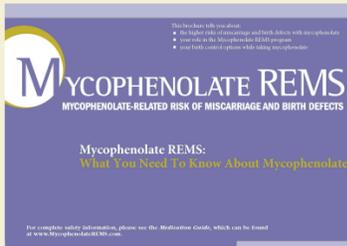
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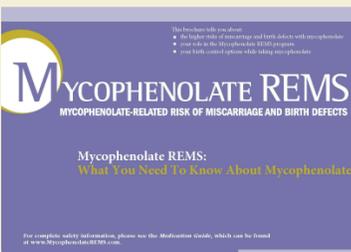
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- You should have one pregnancy test immediately before starting mycophenolate and another pregnancy test 8 to 10 days later to determine if you are pregnant.
- Pregnancy tests should be repeated during routine follow-up visits with your doctor.
-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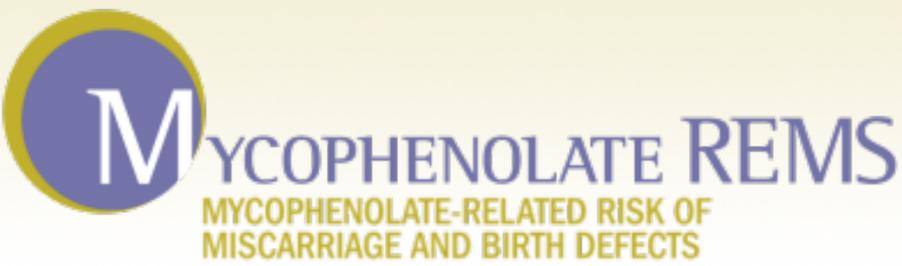
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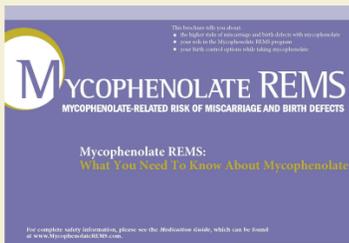
- [+ Understand the risks of taking mycophenolate during pregnancy](#)
 - [+ Do I need to use birth control?](#)
 - [+ Do I need a pregnancy test?](#)
 - [+ What if I am thinking about getting pregnant?](#)
- If you are thinking about having a baby, talk with your doctor right away. Your doctor will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

Report a Pregnancy
To report a pregnancy, click here.

Program Materials
To view program materials online, click here.

Program Resources and Educational Materials

Your Program Materials:



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

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

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Mycophenolate REMS Patient-Prescriber Acknowledgment

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

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

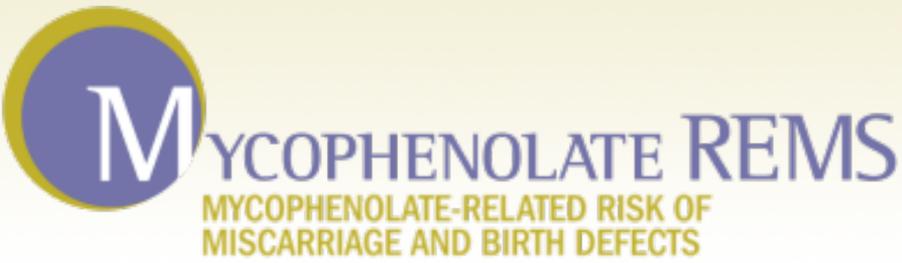
- For prescribers to give to female patients of reproductive potential

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Prescriber
Overview

Patient
Overview

Other Healthcare
Professionals Overview

REMS
Materials

Report a
Pregnancy

Additional
Resources

FAQs

INFORMATION FOR PATIENTS

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

Click an item below to see more information

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

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

You should report your pregnancy to the Mycophenolate Pregnancy Registry?

There are 2 ways to report a pregnancy:

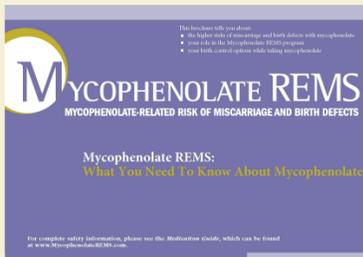
- By phone: **1-800-617-8191**
- Online by clicking this link [Report a Pregnancy](#)



Program Materials

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

Your Program Materials:



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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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Other Healthcare Professionals Overview Page

Accessed from Main Menu link or Other Healthcare Professionals Overview button on Home page

[Prescriber Overview](#)

[Patient Overview](#)

[Other Healthcare Professionals Overview](#)

[REMS Materials](#)

[Report a Pregnancy](#)

[Additional Resources](#)

[FAQs](#)

INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS?

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

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

[+ Step 3 - Report Pregnancies](#)

Program Resources and Educational Materials

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

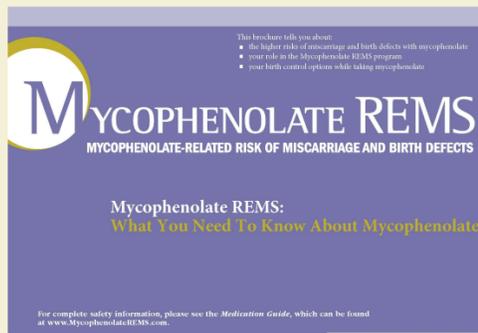
You can view, print, or save the materials to your computer. Select items from the list below.

Your Program Materials:



Mycophenolate REMS Dear Pharmacist Letter

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

- For prescribers to give to female patients of reproductive potential
- Contains the tools and materials to help patients understand the components of the Mycophenolate REMS
- Includes:
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Mycophenolate REMS Healthcare Providers Brochure

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

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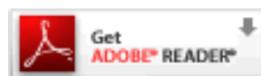
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INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS?

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

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

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

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

+ **Step 3 - Report Pregnancies**

Program Resources and Educational Materials

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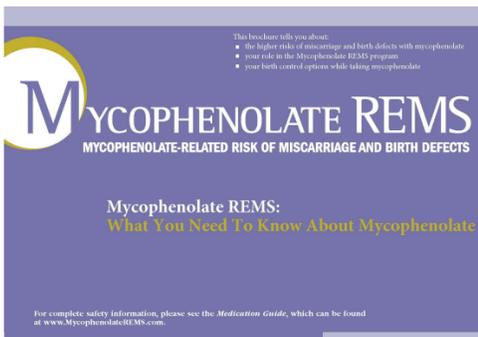
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Mycophenolate REMS Healthcare Providers Brochure

- For prescribers
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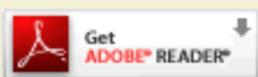
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INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS?

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

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

Counsel these patients:

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

Discuss the following with females of reproductive potential:

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

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

[Print](#)

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

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

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

EMERGENCY CONTRACEPTION

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

+ [Step 3 - Report Pregnancies](#)

Program Resources and Educational Materials

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

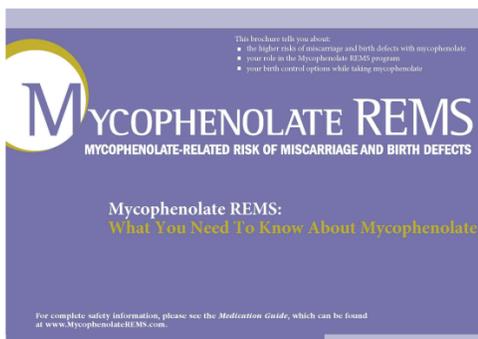
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Mycophenolate REMS Dear Pharmacist Letter

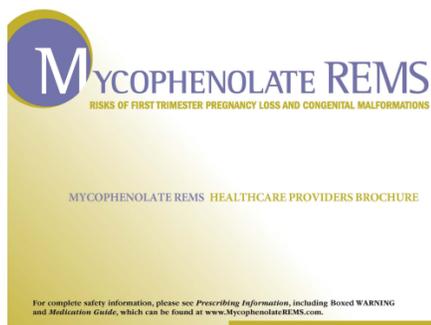
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Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

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

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Mycophenolate REMS Healthcare Providers Brochure

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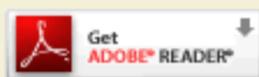
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INFORMATION FOR OTHER HEALTHCARE PROFESSIONALS

What do I need to know about the Mycophenolate REMS?

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

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

+ **Step 3 - Report Pregnancies**

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

There are 2 ways to report a pregnancy:

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

Program Resources and Educational Materials

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

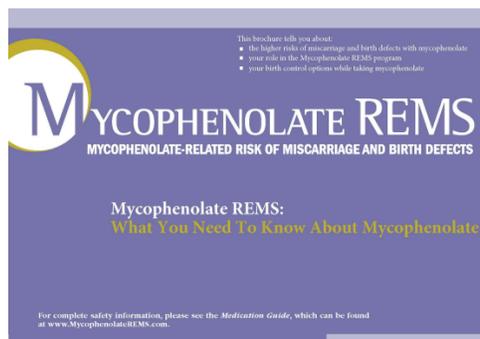
You can view, print, or save the materials to your computer. Select items from the list below.

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Mycophenolate REMS Dear Pharmacist Letter

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

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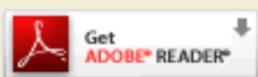
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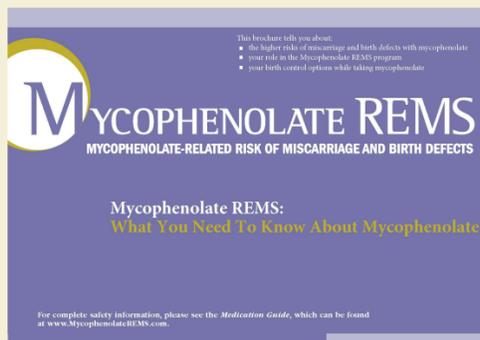


REMS Materials

Accessed from Main menu link on Home Page

Resources and Educational Materials for Prescribers

Your Program Materials:



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

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

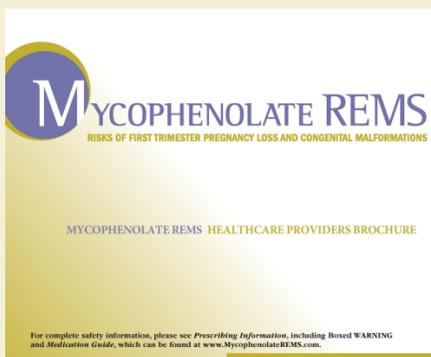
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Mycophenolate REMS Patient-Prescriber Acknowledgment Form

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

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Mycophenolate REMS Healthcare Providers Brochure

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

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Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter

- For prescribers
- Contains important information about the Mycophenolate REMS

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Mycophenolate REMS Dear Healthcare Provider (DHCP) Letter for Centers

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

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Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

- For prescribers to give to female patients of reproductive potential

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Mycophenolate REMS Prescriber Training Confirmation Form

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

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Mycophenolate REMS OBGYN Referral Letter for Contraceptive Counseling

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Mycophenolate REMS OBGYN Referral Letter for Pre-conception Counseling

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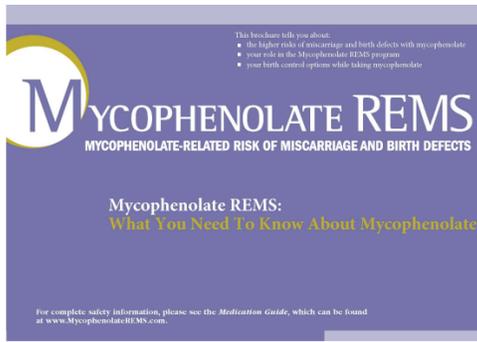
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-

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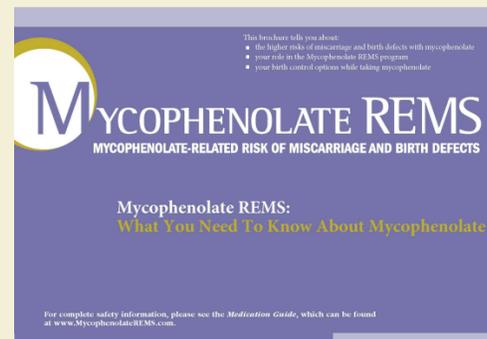
- For prescribers to give to female patients of reproductive potential

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Mycophenolate REMS Dear Pharmacist Letter

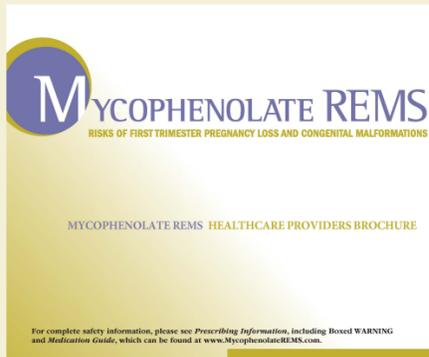
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Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

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- Includes:
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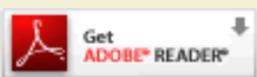
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Report a Pregnancy Page

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

MYCOPHENOLATE PREGNANCY REGISTRY

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

There are 2 ways to report a pregnancy:

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

Patients

I am a pregnant patient, please contact me.

Healthcare Professionals

I am a healthcare professional, please contact me.

What should be reported to the Mycophenolate Pregnancy Registry?

Any pregnancy, planned or unplanned, that occurs:

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

Who should report a pregnancy to the Mycophenolate Pregnancy Registry?

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

What is the Mycophenolate Pregnancy Registry?

The Mycophenolate Pregnancy Registry is a way to collect information about pregnancies in female patients taking mycophenolate or within 6 weeks of stopping treatment. Females taking mycophenolate while they are pregnant have a higher risk of miscarriage in the first 3 months. There is also a higher risk that the baby will have birth defects.

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

[Patient FAQs](#)

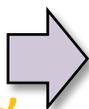
[Prescriber FAQs](#)

I have more questions, where can I get answers?

You can:

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

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



Are You Reporting a Pregnancy?

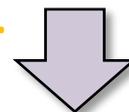
Yes, I have a Pregnancy to Report

No, I need Information about the Registry

No, I Would Like to Return to the Previous Page

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

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



NEW FAQ

What information is collected when a pregnancy is registered?

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

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

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

Additional Resources Page

Accessed from Main menu links

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[Report a
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ADDITIONAL RESOURCES

FOR MORE INFORMATION ABOUT BIRTH DEFECTS

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

FOR MORE INFORMATION ABOUT BIRTH CONTROL

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

FOR EMERGENCY BIRTH CONTROL

- Call your healthcare provider

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

You are now leaving the Web site.

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[Cancel](#)

Frequently Asked Questions (FAQs) Page

Accessed from Main menu links

FREQUENTLY ASKED QUESTIONS

▪ Patients

▪ What is the Mycophenolate REMS ?

The Mycophenolate REMS has been designed to tell you about the risks of taking mycophenolate during pregnancy. Females taking mycophenolate while they are pregnant have a higher risk of miscarriage in the first 3 months. There is also a higher risk that the baby will have birth defects.

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

Patients do not register in the Mycophenolate REMS.

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

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

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

You can fill your prescription in any pharmacy.

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

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

If you are taking mycophenolate, and you are able to get pregnant, you must always use acceptable birth control:

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

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

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

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

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

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

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

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

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

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

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

▪ Where can I find more information about emergency contraception?

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

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

You can talk with your doctor for more information.

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

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

- What is the Mycophenolate Pregnancy Registry?

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

- Why should I take part in the Mycophenolate Pregnancy Registry?

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

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

- Who can take part in the Mycophenolate Pregnancy Registry?

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

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

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

- What will I need to do if I participate in the Mycophenolate Pregnancy Registry?

There are a few simple steps to take.

1. Tell your doctor if you get pregnant

- The Registry will contact you after speaking with your doctor.

2. Complete an *Informed Consent* form

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

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

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

4. Let the Registry know if your contact information changes

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

- What are my rights as a participant in the Mycophenolate Pregnancy Registry?

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

- Whom can I contact for more information?

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

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

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

- How should I store a mycophenolate containing medicine?

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

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

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

- How do I handle internet browser issues?

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

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

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

- What materials will I receive from my doctor?

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

- Prescribers

- Who is Mycophenolate REMS for?

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

- Who can participate in the Mycophenolate Pregnancy Registry?

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

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

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

- Why is the Mycophenolate Pregnancy Registry important?

Exposure to mycophenolate during pregnancy is associated with:

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

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

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

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

- What is my role in the Mycophenolate Pregnancy Registry?

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

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

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

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

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

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

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

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

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

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

- How can I obtain more information?

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

- Pharmacists

- Do pharmacies have to register with the program?

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

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

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

- How can I order more medication guides?

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

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

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

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

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

- Email

- Add Mycophenolate REMS to your safe senders

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

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

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

For Outlook 2000 and Higher

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

Or Follow These Steps

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

Outlook Express (6+)

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

AOL 9.0

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

AOL WebMail

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

Earthlink

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

Entourage

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

Gmail

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

Hotmail

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

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

Yahoo!

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

MacMail

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



Tell a Colleague Page

Accessed from Tell a Colleague link in the header

TELL A COLLEAGUE

**Denotes a required field.*

From (your name)* :

Your email* :

Your colleague's email* :

Email message will be as follows:

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

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

Prescriber Documentation of Training

Accessed from Enroll button on Prescriber Overview page

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[Patient Overview](#)

[Other Healthcare Professionals Overview](#)

[REMS Materials](#)

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PRESCRIBER TRAINING

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

Email :

Re-type Email :

PRESCRIBER TRAINING

Prescriber Training Confirmation

Read and acknowledge the following statements:

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

Mycophenolate is available by prescription as

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

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

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

I agree to do the following:

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

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

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

<< Back

Continue >>

Cancel

PRESCRIBER TRAINING

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

**Denotes a required field.*

Institution :

First Name* :

Last Name* :

Address1* :

Address2 :

City* :

State* :

ZIP* :

Phone* : () -

FAX : () -

NPI Number* :

Degree* :

Specialty* :

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

Authorized Staff Members

[+ Add Staff](#)

[| Legal Statement |](#)

PRESCRIBER TRAINING

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

**Denotes a required field.*

Institution :

First Name* :

Last Name* :

Address1* :

Address2 :

City* :

State* :

ZIP* :

Phone* : ()

FAX : ()

NPI Number* :

Degree* :

Specialty* :

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

Authorized Staff Members

[+ Add Staff](#)

Add/Edit Staff Members Information

First Name* :

Last Name* :

Email* :

Degree* :

Specialty* :

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

[| Legal Statement |](#)

PRESCRIBER TRAINING

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

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

Address : Doctor Doctor
110 Main St
Hatboro, PA 19040

Authorized Staff Members

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

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Continue >>

Cancel

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PRESCRIBER TRAINING

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

Would you like to add another mailing address now?

Yes

No

[<< Back](#)

[Continue >>](#)

[Cancel](#)

| [Legal Statement](#) |

PRESCRIBER TRAINING

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

**Denotes a required field.*

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

[| Legal Statement |](#)

PRESCRIBER TRAINING

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

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

Address : 123 Easton St
Blue Bell, PA 12345

Phone : (987)654-3211

[<< Back](#)

[Continue >>](#)

[Cancel](#)

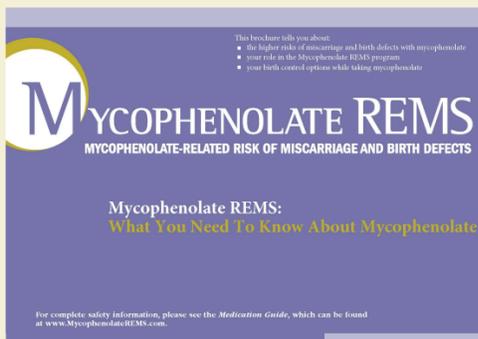
[| Legal Statement |](#)

PRESCRIBER TRAINING

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

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

Your Program Materials:

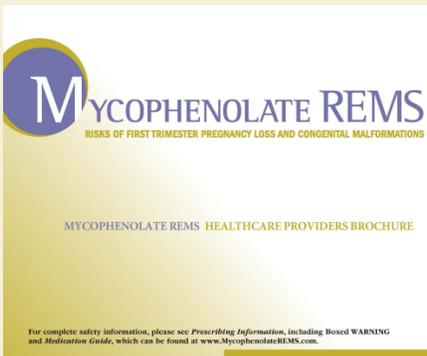


Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate

Qty:

2

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



Mycophenolate REMS Healthcare Providers Brochure

Qty:

1

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

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Cancel

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PRESCRIBER TRAINING

Set your password.

Username is your email address : doctor@yahoo.com

Password : ?

Confirm Password :

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PRESCRIBER TRAINING

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

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

[Finish](#)

[Order Program Materials](#)

Prescriber Login

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

Login Credentials ✕

Prescriber Login

Email :

Password :

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

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

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

Login Credentials

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

Prescriber Login

Email :

Password :

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

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

Add dialogue box

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

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

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

Forgot Password

Accessed from Prescriber Login Screen as a link



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[Other Healthcare Professionals Overview](#)

[REMS Materials](#)

[Report a Pregnancy](#)

[Additional Resources](#)

INFORMATION FOR PRESCRIBERS

What is my role in the Mycophenolate REMS Program?

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

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

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

Login Credentials ✕

Forgot Password

Email :

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

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

Report a Pregnancy

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

Prescriber Training

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

Program Materials

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

Document Your Training

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

Prescriber Order Materials

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

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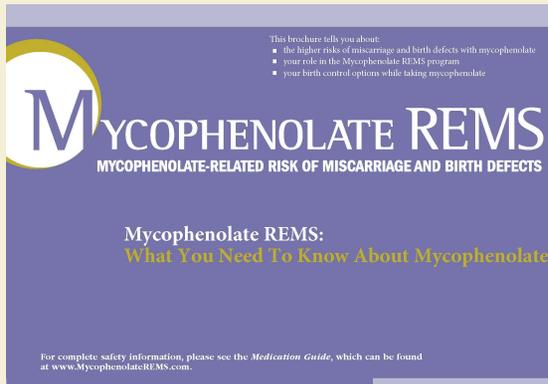
[FAQs](#)

ORDER MATERIALS

Step 1 of 4: Select Materials

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

Your Program Materials:



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

Qty:

0

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



Mycophenolate REMS Patient-Prescriber Acknowledgment

Qty: 0

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



Mycophenolate REMS Healthcare Providers Brochure

Qty: 0

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



Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients

Qty: 0

- For prescribers to give to female patients of reproductive potential



Mycophenolate REMS Prescriber Training Confirmation Form

Qty:

0

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

Continue >>

Cancel

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

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ORDER MATERIALS

Step 2 of 4: Select Shipping Address

Please select a shipping address.

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

[<< Back](#)

[Continue >>](#)

[Cancel](#)

ORDER MATERIALS

Step 3 of 4: Confirm Order Information

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

Review and confirm your order information :

Ordered Items	
Qty	Item
1	Mycophenolate REMS Prescriber Training Confirmation Form

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

[<< Back](#)

[Submit Order](#)

[Cancel](#)

ORDER MATERIALS

Step 4 of 4: Order Completed

Order Complete

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

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

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

[Finish](#)



Welcome **Test_User**

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

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[FAQs](#)

ORDER MATERIALS

Step 4 of 4: Order Completed

Order Complete

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

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

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

[Finish](#)

Edit My Profile

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

VIEW AND EDIT MY PROFILE

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

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

/s/

OZLEM A BELEN
11/13/2015