

PRESCRIBER TRAINING CONFIRMATION FORM

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

Mycophenolate is available by prescription as

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

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

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

I agree to do the following:

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

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

Please Print:

Prescriber First Name: _____ Prescriber Last Name: _____

Prescriber Degree: (Circle one) MD DO NP PA

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

Prescriber E-mail Address: _____

Facility: _____

Address 1: _____

Address 2: _____

City: _____ State: _____ ZIP: _____

Telephone: _____ Fax: _____

Prescriber Signature: _____ Date: _____

Healthcare Provider acting on behalf of the prescriber: _____

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

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

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

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

Mycophenolate REMS
[Current Vendor Address]

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

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

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