

CENTER TRAINING CONFIRMATION FORM

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

Mycophenolate is available by prescription as:

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

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

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

We agree to do the following:

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

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

(Please fill out form on next page)

CENTER TRAINING CONFIRMATION FORM
CENTER INFORMATION

(PLEASE PRINT)

Center: _____

Center Type (disease or specialty)*: _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: _____ Fax: _____

Contact Person: _____ E-mail: _____

TRAINED PRESCRIBERS

Please complete fields below:

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

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

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

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

Mycophenolate REMS
 [Current Vendor Address]

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

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