

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 contact the Mycophenolate REMS Coordinating Center at 1-800-617-8191 for the mailing 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 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