

## 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](http://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](http://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):

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# MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS AND CONGENITAL MALFORMATIONS

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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](http://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](http://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







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