# PRESCRIBER TRAINING CONFIRMATION FORM

MYCOPHENOLATE REMS
RISKS OF FIRST TRIMESTER PREGNANCY LOSS AND CONGENITAL MALFORMATIONS

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The FDA determined that a REMS (Risk Evaluation and Mitigation Strategy) is necessary to ensure that the benefits of mycophenolate outweigh the 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 females of reproductive potential,* I understand that I need to complete and return the *Training Confirmation Form* to enroll in 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 the full *Prescribing Information* for mycophenolate and the *Mycophenolate REMS Brochure for Healthcare Providers*.
2. Understand the 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 Overview & Your Birth Control Options* booklet 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 Brochure for Healthcare Providers*.
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 *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)

Complete all fields below:

Prescriber First Name: _____ Prescriber Last Name: _____

Prescriber Degree: MD, DO, NP, PA (Circle One)

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: RN, LPN, NP, PA, RPH, PharmD, CSW (Circle One)

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

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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 or mail it to:

Mycophenolate REMS
200 Pinecrest Plaza
Morgantown, WV 26505-8065

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 |