MYCOPHENOLATE REMS
RISKS OF FIRST TRIMESTER PREGNANCY LOSS AND CONGENITAL MALFORMATIONS

IMPORTANT DRUG WARNING
Regarding Mycophenolate-Containing Products

Important Updates from the Mycophenolate REMS*

Dear Healthcare Provider:

If you prescribe mycophenolate containing products, you should be aware that there are **increased risks of first trimester pregnancy loss and congenital malformations** associated with exposure to mycophenolate during pregnancy. However, a recent survey of female patients taking mycophenolate during reproductive age indicates that **many patients do NOT understand these risks.**

Have the important conversation with your patients:

With your involvement, we can improve patient understanding and reduce the number of unplanned pregnancies to women taking mycophenolate.

Discuss the following with your female patients of reproductive potential:

- The **increased risks** of first trimester pregnancy loss and congenital malformations while taking mycophenolate.
- **Pregnancy tests** should to be conducted before and during mycophenolate treatment.
- **Birth control** needs to be used while taking mycophenolate, and for 6 weeks after stopping treatment, to avoid pregnancy.
- **Pregnancy planning** needs to be discussed with a healthcare provider if a patient wishes to become pregnant during mycophenolate treatment.
- **All pregnancies** need to be **reported** to the mycophenolate pregnancy registry, 1-800-617-8191, or online at www.mycophenolatepregnancyregistry.com, or www.MycophenolateREMS.com.

Training tools are available for patients:

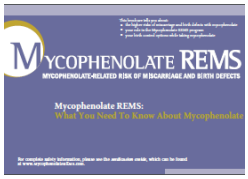
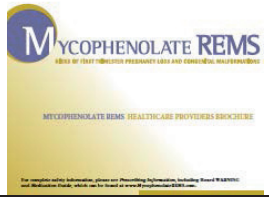
- **Mycophenolate REMS Patient Brochure: What You Need to Know About Mycophenolate**. This brochure discusses the risks of pregnancy loss and birth defects, birth control options and information on the mycophenolate REMS program.
- **Mycophenolate REMS Prescriber-Patient Acknowledgement Form.** This form can be used to discuss the risks associated with use of mycophenolate. Prescribers and patients should sign this form.

Materials are available at www.MycophenolateREMS.com or by calling **1-800-617-8191.**
A list of available tools is found on the back of this letter.

Thank you for your commitment to helping female patients of reproductive potential understand the risks and benefits associated with mycophenolate treatment.

Sincerely,
Mycophenolate REMS Team

*The Mycophenolate REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to tell healthcare providers and patients about the risks of taking mycophenolate during pregnancy.

Training Tools		Web Link Or How To Order
	**Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate**	https://www.mycophenolaterems.com/Docs/PatientResourceKit.pdf
	**Mycophenolate REMS Patient-Prescriber Acknowledgement Form**	https://www.mycophenolaterems.com/Docs/PatientAgreement.pdf
	**Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients**	https://www.mycophenolaterems.com/Docs/PatientRegistryFAQ.pdf
	**Mycophenolate REMS Healthcare Provider Brochure**	https://www.mycophenolaterems.com/Docs/PrescriberProgramBrochure.pdf
	**Medication Guides**	https://www.mycophenolaterems.com/SafetyInformation.aspx