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, 2014 and 2017 REMS Assessment surveys of female patients taking mycophenolate during reproductive age indicated that **many patients do NOT understand these risks.**

Discuss the following with your female patients of reproductive potential:

- The **increased risks** of miscarriage and birth defects 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.
- **Report pregnancies** to the Mycophenolate Pregnancy Registry, 1-800-617-8191, or online at www.MycophenolateREMS.com.

A training tool is available for patients:

- **Patient Information Brochure: What You Need to Know About Mycophenolate**. This brochure discusses the risks of miscarriage, birth defects, birth control options and information on the Mycophenolate REMS.

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.**

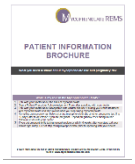
REMS-compliant accredited, independent Continuing Education (CE) is available for healthcare providers who prescribe and/or participate in the treatment of patients taking mycophenolate products.

- Please visit www.MycophenolateREMS.com or call 1-800-617-8191 for additional information on Continuing Education (CE).

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 inform healthcare providers and patients about the risks of taking mycophenolate during pregnancy.

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