



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.mycophenolatepregnancyregistry.com](http://www.mycophenolatepregnancyregistry.com), or [www.MycophenolateREMS.com](http://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](http://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 inform healthcare providers and patients about the risks of taking mycophenolate during pregnancy.

Training Tools		Web Link Or How To Order
	<p><b>Patient Information Brochure: What You Need To Know About Mycophenolate</b></p>	<p><a href="https://www.mycophenolate.rems.com/Docs/PatientResourceKit.pdf">https://www.mycophenolate.rems.com/Docs/PatientResourceKit.pdf</a></p>
	<p><b>Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients</b></p>	<p><a href="https://www.mycophenolate.rems.com/Docs/PatientRegistryFAQ.pdf">https://www.mycophenolate.rems.com/Docs/PatientRegistryFAQ.pdf</a></p>
	<p><b>Healthcare Provider Brochure</b></p>	<p><a href="https://www.mycophenolate.rems.com/Docs/PrescriberProgramBrochure.pdf">https://www.mycophenolate.rems.com/Docs/PrescriberProgramBrochure.pdf</a></p>
	<p><b>Medication Guides</b></p>	<p><a href="https://www.mycophenolate.rems.com/SafetyInformation.aspx">https://www.mycophenolate.rems.com/SafetyInformation.aspx</a></p>