



IMPORTANT DRUG WARNING  
Regarding Mycophenolate-Containing Products

**Important Updates from the Mycophenolate REMS\***

Dear Center Director:

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.

Surveys of female patients taking mycophenolate during reproductive age indicated that **many patients do NOT understand these risks.**

**Discuss the following with 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 mycophenolate treatment, to avoid pregnancy.
- **Pregnancy planning** needs to be discussed with a healthcare provider if a patient wishes to become pregnant during mycophenolate treatment.

The Mycophenolate Pregnancy Registry has been established to evaluate mycophenolate-exposed pregnancies and their outcomes. Consider sharing with patients the **Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients**, which is available on [www.MycophenolateREMS.com](http://www.MycophenolateREMS.com).

- **Report pregnancies to the Mycophenolate Pregnancy Registry, 1-800-617- 8191, or online at [www.MycophenolateREMS.com](http://www.MycophenolateREMS.com).**

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

For more information about Mycophenolate REMS, including all program materials and instructions on how to enroll, please visit [www.MycophenolateREMS.com](http://www.MycophenolateREMS.com) or call **1-800-617-8191**.





**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](http://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
	<b>Patient Information Brochure: What You Need To Know About Mycophenolate</b>	<a href="https://www.mycophenolate.rems.com/Docs/PatientResourceKit.pdf">https://www.mycophenolate.rems.com/Docs/PatientResourceKit.pdf</a>
	<b>Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients</b>	<a href="https://www.mycophenolate.rems.com/Docs/PatientRegistryFAQ.pdf">https://www.mycophenolate.rems.com/Docs/PatientRegistryFAQ.pdf</a>
	<b>Healthcare Provider Brochure</b>	<a href="https://www.mycophenolate.rems.com/Docs/PrescriberProgramBrochure.pdf">https://www.mycophenolate.rems.com/Docs/PrescriberProgramBrochure.pdf</a>
	<b>Medication Guides</b>	<a href="https://www.mycophenolate.rems.com/SafetyInformation.aspx">https://www.mycophenolate.rems.com/SafetyInformation.aspx</a>