IMPORTANT DRUG WARNING



Regarding Mycophenolate-Containing Products

Important Updates From the Mycophenolate REMS*

Dear Pharmacist:

Female patients of reproductive potential that are prescribered mycophenolate containing products, patients need to be aware that there are increased risks of first trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy. A recent survey of female patients taking mycophenolate during reproductive age indicates that many patients do NOT understand these risks.

To help improve the understanding of female patients of reproductive potential on these risks, the Mycophenolate REMS program is asking that you counsel these patients.

Female patients of reproductive potential need to understand the following:

- The **increased risks** of first trimester pregnancy loss and congenital malformations while taking mycophenolate.
- **Pregnancy tests** need 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.
- **All pregnancies** need to be **reported** to the mycophenolate pregnancy registry, 1-800-617-8191, or online at www.mycophenolatepregnancyregistry.com or at www.mycophenolateREMS.com.

These risks are addressed by the Mycophenolate REMS program.

Educational tools are available to use with these patients. All materials are available atwww.MycophenolateREMS.com or by calling 1-800-617-8191.

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

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^{*}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
YCOPHENOLATE REMS Mycophenolate REMS Mycophenolate REMS Mycophenolate REMS	Mycophenolate REMS Patient Brochure: What You Need To Know About Mycophenolate	https://www.mycophenolate rems.com/Docs/PatientReso urceKit.pdf
Current TO TO THE PROPERTY OF	Mycophenolate REMS Patient-Prescriber Acknowledgement Form	https://www.mycophenolate rems.com/Docs/PatientAgre ement.pdf
Comment and Amendment and the second and the secon	Mycophenolate Pregnancy Registry Frequently Asked Questions for Patients	https://www.mycophenolate rems.com/Docs/PatientRegi stryFAQ.pdf
YCOPHENOLATE REMS THE OF THE PROPERTY SHEET OF THE SHEET PROPERTY SHEET	Mycophenolate REMS Healthcare Provider Brochure	https://www.mycophenolate rems.com/Docs/PrescriberP rogramBrochure.pdf
Service Billion Digital Billion Service Servic	Medication Guides	https://www.mycophenolate rems.com/SafetyInformatio n.aspx