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JOURNAL INFORMATION

IMPORTANT SAFETY INFORMATION FOR
PRESCRIBERS OF MYCOPHENOLATE



MYCOPHENOLATE REMS

RISKS OF FIRST TRIMESTER PREGNANCY LOSS AND CONGENITAL MALFORMATIONS

Mycophenolate REMS (Risk Evaluation and Mitigation Strategy) has been mandated by the FDA (Food and Drug Administration) due to postmarketing reports showing that **exposure to mycophenolate during pregnancy is associated with increased risks of first trimester pregnancy loss and congenital malformations.**

Mycophenolate is available by prescription as

- CellCept® (mycophenolate mofetil)
- Myfortic® (mycophenolic acid)
- Generic formulations of mycophenolate mofetil
- Generic formulations of mycophenolic acid

The goals of Mycophenolate REMS are

1. To prevent unplanned pregnancy in patients using mycophenolate and to minimize fetal exposure to mycophenolate by informing prescribers and females of reproductive potential about
 - The increased risks of first trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy; and
 - The importance of pregnancy prevention and planning
2. To minimize the risks associated with fetal exposure to mycophenolate by collecting information on pregnancy outcomes through the Mycophenolate Pregnancy Registry
3. To inform patients about the serious risks associated with mycophenolate

What you need to know to prescribe mycophenolate

All prescribers of mycophenolate and females of reproductive potential, whether or not they plan to get pregnant, should participate in Mycophenolate REMS.

Mycophenolate Pregnancy Registry

It is important for healthcare providers to report any pregnancies of which they become aware that occur during treatment with mycophenolate or within 6 weeks following discontinuation of treatment. The Mycophenolate Pregnancy Registry has been established to evaluate mycophenolate-exposed pregnancies and their outcomes. Pregnancies should be reported by contacting the Mycophenolate Pregnancy Registry at 1-800-617-8191.

Visit www.MycophenolateREMS.com or call 1-800-617-8191 to access all resource materials.

For complete safety information, please see full *Prescribing Information*, including Boxed WARNING and Medication Guide, which can be found at www.MycophenolateREMS.com