Important Safety Information Regarding Mycophenolate
Introducing the MANAGE℠ Program

Dear Prescriber:

The purpose of this letter is to inform you of important safety information for mycophenolate. The MANAGE Program is part of a REMS (Risk Evaluation and Mitigation Strategy) for mycophenolate that has been mandated by the FDA (Food and Drug Administration) due to postmarketing reports showing that exposure to mycophenolate during pregnancy is associated with an increased risk of miscarriage and congenital malformations. The FDA has determined that a REMS is necessary for mycophenolate to ensure the benefits of the drug outweigh the risks associated with exposure to mycophenolate during pregnancy.

Mycophenolate is available by prescription as

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

The goals of the MANAGE Program are

- To prevent unplanned pregnancy in female patients of childbearing potential
- To provide pregnancy planning education by informing prescribers, nurses, pharmacists and female patients of childbearing potential of the risks associated with exposure to mycophenolate during pregnancy
- To collect information on fetal outcomes through the MANAGE Pregnancy Registry

All prescribers of mycophenolate and female patients of childbearing potential, whether or not they plan to get pregnant, are required by the FDA to participate in the MANAGE Program. A female of childbearing potential includes young women who have entered puberty but have not yet started menstruating, and all women who have had at least 1 menstrual period in the last 12 months.

If you prescribe mycophenolate to female patients of childbearing potential, you must enroll in the MANAGE Program and attest that you

1. Will reenroll in the MANAGE Program annually.
2. Have read and you understand the *Medication Guide*, full *Prescribing Information* for mycophenolate and the MANAGE Program educational material.
3. Will ensure female patients are not pregnant prior to initiating or continuing treatment. You will ensure that patients have 2 negative serum or urine pregnancy tests 8 to 10 days apart with a sensitivity of at least 25 mIU/mL prior to initiating treatment.
4. Will provide a *Medication Guide* and MANAGE Program educational material to female patients of childbearing potential.
5. Will educate female patients on the risks associated with exposure to mycophenolate during pregnancy.
6. Will provide contraceptive counseling and pregnancy planning education to patients directly or by partnering with an OB/GYN.
7. Will report to the MANAGE Pregnancy Registry any pregnancies that occur during treatment with mycophenolate or within 6 weeks following discontinuation of treatment. You will also encourage female patients to participate in the MANAGE Pregnancy Registry.
8. Will obtain a signed *Patient Agreement and Responsibilities* form from patients.

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for important safety information.

Please note that the program sponsors may contact you in the future for assessment of the MANAGE Program.

This letter is not a comprehensive description of the risks associated with the use of mycophenolate. For more information about the MANAGE Program, including all program materials and instructions on how to enroll, please visit **www.ManageProgram.com** or call **1-800-617-8191**.

The FDA requires healthcare professionals to report any pregnancies of which they become aware. Pregnancies that occur during treatment with mycophenolate or within 6 weeks following discontinuation of treatment should be reported by contacting the MANAGE Pregnancy Registry

- By phone: **1-800-617-8191**
- Online: **www.ManagePregnancyRegistry.com**
- Or by mail: MANAGE Pregnancy Registry
  201 Broadway, Suite 5
  Cambridge, MA 02139

Thank you for your commitment to helping patients understand the risks and benefits associated with mycophenolate treatment.

Sincerely,

MANAGE Team

Please see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide, for important safety information.