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# MYCOPHENOLATE REMS HOMEPAGE

## WELCOME TO THE MYCOPHENOLATE REMS (Risk Evaluation and Mitigation Strategy)

### What is the Mycophenolate REMS?

The Mycophenolate REMS is a program to tell doctors, nurses, pharmacists and patients about the risks of taking mycophenolate during pregnancy. It was mandated by the Food and Drug Administration (FDA).

### What medications contain mycophenolate?

#### Mycophenolate Mofetil

CellCept® by Genentech USA, Inc.

[Generic formulations by >>](#)

#### Mycophenolic Acid

Myfortic® by Novartis Pharmaceuticals Corporation.

[Generic formulations by >>](#)

### Who should be informed about the Mycophenolate REMS?

- Doctors who prescribe mycophenolate.
- Females of reproductive potential\* who are taking mycophenolate.
- Pharmacists who dispense medicines with mycophenolate in them.



#### Prescribers

To enroll or order materials, [click here](#)



#### Pharmacists

For Pharmacists Overview [click here](#)



#### Patients

For Patient Overview, [click here](#)

### Why did the FDA mandate the Mycophenolate REMS?

The FDA determined that a REMS (Risk Evaluation and Mitigation Strategy) is necessary to ensure that the benefits of mycophenolate outweigh the risks of first trimester pregnancy loss and congenital malformations associated with mycophenolate use during pregnancy.

- Higher risk of miscarriage in the first 3 months.
- Higher risk that the baby will have birth defects.

### What are the goals of the Mycophenolate REMS?

The goals of the Mycophenolate REMS are:

- 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
- To minimize the risks associated with fetal exposure to mycophenolate by collecting information on pregnancy outcomes through the Mycophenolate Pregnancy Registry.
- To inform patients about the serious risks associated with mycophenolate.

\*Females of reproductive potential include girls who have entered puberty and all women who have a uterus and have not passed through menopause.

