

# Mycophenolate REMS Website Screenshots

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

Looking for Accredited REMS CME/CE Activities?

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### What is the Mycophenolate REMS?

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

### What are the risks of mycophenolate during pregnancy?

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

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

#### Prescribers

For Prescriber Overview,  
[click here](#)

#### Patients

For Patient Overview,  
[click here](#)

#### Other Healthcare Professionals

For Other Healthcare Professionals,  
[click here](#)

### What is the goal of the Mycophenolate REMS?

The goal of the Mycophenolate REMS is to mitigate the risk of embryofetal toxicity associated with the use of mycophenolate during pregnancy by:

1. Educating healthcare providers on the following:
  - The increased risks of miscarriage and birth defects associated with exposure to mycophenolate during pregnancy.
  - The need to counsel females of reproductive potential on the importance of pregnancy prevention and planning when taking mycophenolate.
  - The need to report pregnancies to the Mycophenolate Pregnancy Registry.
2. Informing females of reproductive potential who are prescribed mycophenolate about:
  - The increased risks of pregnancy loss (miscarriage) and birth defects.
  - The importance of pregnancy prevention and planning when taking mycophenolate.

### What medications contain mycophenolate?

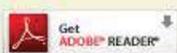
Mycophenolate Mofetil  
CellCept® by Genentech USA, Inc.

[Generic formulations by >>](#)

Mycophenolic Acid  
Myfortic® by Novartis Pharmaceuticals Corporation.

[Generic formulations by >>](#)

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



# CME/CE Activities Page

Accessed from the banner on the Home Page, Prescriber Overview Page,  
and Other Healthcare Professional Page



## ACCREDITED REMS CME/CE ACTIVITIES

The goal of the Mycophenolate REMS is to mitigate the risk of embryofetal toxicity associated with the use of mycophenolate by:

1. Educating healthcare providers on the following:
  - The increased risks of first trimester pregnancy loss and congenital malformations associated with exposure to mycophenolate during pregnancy.
  - The need to counsel females of reproductive potential on the importance of pregnancy prevention and planning when taking mycophenolate.
  - The need to report pregnancies to the Mycophenolate Pregnancy Registry.
2. Informing females of reproductive potential who are prescribed mycophenolate about:
  - The increased risks of pregnancy loss (miscarriage) and birth defects.
  - The importance of pregnancy prevention and planning when taking mycophenolate.

As part of the Mycophenolate REMS, the Mycophenolate Applicants must provide training for healthcare providers who prescribe and/or participate in the treatment of patients taking mycophenolate products. This training includes accredited CME/CE activities developed by accredited CME/CE Providers and offered to healthcare providers at no cost.

The FDA has developed a FDA Blueprint for the Mycophenolate REMS, which contains a high-level outline of the core educational messages that must be addressed in the educational programs developed under the Mycophenolate REMS. The core messages are directed to healthcare providers who prescribe and/or participate in the treatment of patients taking mycophenolate products.

A list of available REMS CME/CE activities offered by accredited CME/CE Providers and supported by independent commercially-supported educational grants from the Mycophenolate Applicants appears below. To access these accredited CME/CE activities, click on any link in the Table below.

Program Title	Accredited CME/CE Provider	Link to CME/CE Activity

The Mycophenolate Applicants attest that this table will be populated once grants are approved and will include the list of available CME/CE activities.

# Prescriber Overview Page

Accessed from Main menu links or Prescribers button on Home Page