

Healthcare Professional Communication Guide

Mitigating Pregnancy Risks When Prescribing Mycophenolate Products



Mycophenolate mofetil and mycophenolic acid are approved by the FDA for the prevention of solid organ transplant rejection and are used off-label for systemic lupus erythematosus, lupus nephritis, and other autoimmune conditions

The FDA requires a Risk Evaluation and Mitigation Strategy (REMS) program.

Risks associated with mycophenolate use during pregnancy

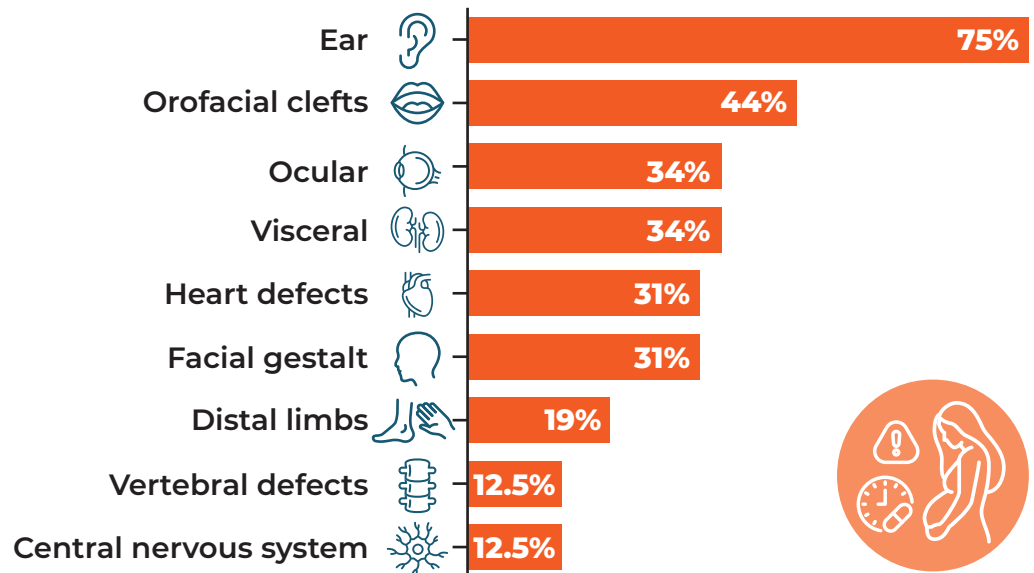
30%-45%

Miscarriage

9%-22%

Birth defects

Characteristics of mycophenolate birth defects



How to Mitigate Mycophenolate Pregnancy Risks

Education is essential for all prescribers and dispensers of mycophenolate and for patients who can become pregnant who are prescribed mycophenolate.

- Document REMS training at MycophenolateREMS.com OR PSMycophenolateREMS.com
- Educate patients about:
 - Increased risks of mycophenolate exposure
 - Pregnancy planning
 - Contraception and birth control options
 - The Mycophenolate Pregnancy Registry and the benefits of enrolling
 - Methods of reporting a pregnancy:
 - MycophenolateREMS.com/#Main/ReportaPregnancy
 - PSMycophenolateREMS.com/Report-a-Pregnancy
- Test for pregnancy before, throughout, and for 6 weeks after mycophenolate treatment

Watch this roundtable to learn more!



Acceptable Birth Control Options

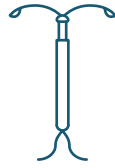
Talk with your healthcare team and pick from the following birth control options during treatment with mycophenolate

A

Option 1: Can Use Alone
(pick one item from A)

Most effective:

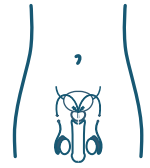
Less than 1 pregnancy per 100 women in 1 year



Intrauterine device (IUD)



Tubal sterilization



Vasectomy

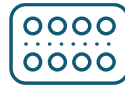
B

Option 2: Use Hormone and Barrier (pick one from B **and** one from C1 or C2 shown below)

4-7 pregnancies per 100 women in 1 year



Progesterone only injection



Birth control pill



Birth control (progesterone) patch



Vaginal ring



Progesterone implant

IMPORTANT:

Mycophenolate drugs can reduce the effectiveness of birth control pills and hormonal contraceptives. Therefore, you **MUST ALSO** use a barrier method—such as a condom or diaphragm with a spermicide—to avoid becoming pregnant.

C

Option 3: Use 2 Barriers
(pick one from C1 **and** one from C2)

Least effective:

13 or more pregnancies per 100 women in 1 year

1



Internal condom



External condom

2



Diaphragm with spermicide



Birth control sponge



Cervical cap with spermicide

Employ Shared Decision-making About Family Planning

- Reevaluate treatment options for patients who want to become pregnant
 - Discuss alternate treatments
 - Design a transition plan
 - Consult with other healthcare professional specialists
- Refer patients for preconception counseling and high-risk obstetrical care as needed
- Coordinate care among the patient's established healthcare professionals

For more information about mycophenolate risks, visit [MycophenolateREMS.com](https://www.MycophenolateREMS.com)
OR [PSMycophenolateREMS.com](https://www.PSMycophenolateREMS.com)



◀ Scan here to view a **patient education pamphlet** on mycophenolate risks
Scan here to watch a **pharmacist consultation** for mycophenolate risks ▶▶



This educational sheet is jointly provided by Boston University Chobanian & Avedisian School of Medicine, in partnership with Clinical Care Options, LLC. Its production was supported by an independent educational grant from the Mycophenolate REMS Group and is intended to be fully compliant with the Mycophenolate REMS education requirements as issued by the US Food and Drug Administration (FDA).



Chobanian & Avedisian School of Medicine
Barry M. Manuel Center for Continuing Education



powered by CEA