

((Date))

((Recipient's Name))
 ((Recipient's Address 1))
 ((Recipient's Address 2))
 ((City, State, ZIP))

In reference to: My patient ((Patient's Name))
 Reason for the referral: Contraception counseling

Dear Dr ((Recipient's Last Name)):

I am writing to you in reference to the above-named patient who is under my care for ((diagnosis)) and ((insert drug information such as drug name, when patient will begin taking the drug, if treatment has already begun, etc)). This medication contains mycophenolate, which is associated with an increased risk of first trimester pregnancy loss and congenital malformations. It is important that this patient receive contraception counseling about methods that are acceptable for use while taking mycophenolate.

Prescribers of mycophenolate participate in the FDA-required Mycophenolate REMS (Risk Evaluation and Mitigation Strategy) to ensure that the benefits of mycophenolate outweigh the risks.

The following table lists the forms of contraception that are acceptable for use during treatment with mycophenolate.

Acceptable Contraception Methods for Females of Reproductive Potential
Guide your patients to choose from the following birth control options:

| | |
|-----------------------------|---|
| Option 1 | <ul style="list-style-type: none"> ■ Intrauterine devices (IUDs) ■ Tubal sterilization ■ Patient's partner had a vasectomy |
| Methods to Use Alone | |

OR

| | | | |
|---|--|------------|---|
| Option 2 | Hormone Methods choose 1 | | Barrier Methods choose 1 |
| Choose One Hormone Method AND One Barrier Method | Estrogen and Progesterone | <i>AND</i> | <ul style="list-style-type: none"> ■ Diaphragm with spermicide ■ Cervical cap with spermicide ■ Contraceptive sponge ■ Male condom ■ Female condom |
| | <ul style="list-style-type: none"> ■ Oral contraceptive pill ■ Transdermal patch ■ Vaginal ring Progesterone-only <ul style="list-style-type: none"> ■ Injection ■ Implant | | |

OR

| | | | |
|---|---|------------|--|
| Option 3 | Barrier Methods choose 1 | | Barrier Methods choose 1 |
| Choose One Barrier Method From Each Column (must choose two methods) | <ul style="list-style-type: none"> ■ Diaphragm with spermicide ■ Cervical cap with spermicide ■ Contraceptive sponge | <i>AND</i> | <ul style="list-style-type: none"> ■ Male condom ■ Female condom |

Patients should be aware that mycophenolate reduces blood levels of the hormones in the oral contraceptive pill and could reduce its effectiveness. An additional barrier method must be used with any hormonal contraceptives.

Patients should also be counseled on the availability of emergency contraception.

Unless patients choose to remain abstinent, they should be instructed to use acceptable birth control during the entire treatment with mycophenolate and for 6 weeks after they stop taking mycophenolate.

You can find more information about Mycophenolate REMS, including the roles and responsibilities of patients and prescribers of mycophenolate, at www.MycophenolateREMS.com. The site provides educational materials, as well as access to *Prescribing Information* and *Medication Guides* for mycophenolate-containing products.

Please call me at ((Signatory's phone)) at your earliest convenience. Thank you for your cooperation.

Sincerely,

((Signatory's Name))

((Signatory's Practice))