The Transplant Center

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Boston.



Mycophenolate Medication Information

What is mycophenolate mofetil?

Mycophenolate mofetil is an immunosuppressant in the class of drugs known as antiproliferatives. This drug is used to suppress your immune system so your body does not reject your transplanted organ. Other medications such as calcineurin inhibitors (cyclosporine or tacrolimus) and corticosteroids (Prednisone) may also be used with mycophenolate to help prevent rejection. Mycophenolate mofetil may also be used in some cases to treat illnesses such as Lupus, Crohn's disease and ulcerative colitis before your transplant.

Are there other names for mycophenolate mofetil?

Yes, mycophenolate mofetil may be referred to by its brand name which is Cellcept® or by its shorter abbreviated name MMF.

Is mycophenolate mofetil available in a generic formulation or any other formulation that I should be aware of?

Generic formulations of mycophenolate mofetil are available as of May 2009. It is anticipated the BIDMC in-patient pharmacy will begin dispensing generic mycophenolate mofetil in early 2010. If you are started on generic mycophenolate mofetil when you are in the hospital and you are discharged on generic mycophenolate mofetil you will be followed regularly. If you are discharged from the hospital on brand name mycophenolate mofetil and you are later switched to generic mycophenolate mofetil by your pharmacy you must notify you transplant coordinator. Additionally, if you receive a generic mycophenolate mofetil product that looks different than the generic product you may already be taking you should call you transplant coordinator. It is important that you remain on the same generic pill at all times and do not switch between generics. There are currently 7 different makes of generic mycophenolate mofetil.

There is another formulation of Mycophenolate available called Mycophenolate Sodium (brand name Myfortic®). Your pharmacy can not give you Myfortic® in place Cellcept® unless it is ordered specifically. Myfortic® may be an option for patients who can not tolerate the side effects of Cellcept®.

This table will help you identify your gernic mycophenolate mofetil. If your pills appearance changes be sure to notify you transplant coordinator.

Manufacturer	250 mg Capsule	500 mg Tablet
	Description	Description
Apotex	Opaque blue cap over opaque pink body; M250 and APO imprinted in black ink	Lavender-colored, capsule-shaped, film-coated tablet (unscored); APO (side 1), MYC500 (side 2)
Mylan	Caramel opaque cap over lavender opaque body; MYLAN over 2255 imprinted in black ink on cap and body	Light pink oval tablet; MYLAN (side 1), 472 (side 2)
Roxane	Blue opaque cap over caramel opaque body; 54848 imprinted in black ink on cap and body	White, film-coated oval-shaped tablet; 54 135 (side 1), no marking on side 2
Sandoz	Blue opaque cap and white opaque body; 655 imprinted in black ink on cap and body	Lavender-color film-coated biconvex tablet; imprinted with SZ (side 1) and 327 (side 2)



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Manufacturer	250 mg Capsule Description	500 mg Tablet Description
Teva	Light blue opaque cap over bright orange opaque body; 93 over 7334 imprinted in black ink on cap and body	Purple, oval-shaped, film-coated tablets; debossed with 93 (side 1), 7477 (side 2)
Zydus	Opaque blue cap over opaque white body; imprinted with 130 in black ink	White to off-white, capsule-shaped, biconvex film- coated tablets; imprinted with ZA49 (side 1), no marking on side 2
Accord	Light blue cap and peach body; two bar lines imprinted on cap and body	Purple-color, capsule-shaped, biconvex, film-coated tablets; debossed AHI (side 1) and 500 (side 2)
Roche (CellCept®)	Blue cap over peach body; CellCept 250 (side 1), Roche (side 2) printed with black ink	Lavender capsule-shaped coated tablet; CellCept 500 (side 1), Roche (side 2)

How do I take mycophenolate?

Follow your physician's instructions carefully. Mycophenolate should be taken at the same time each day to maintain a steady blood level. Most patients take it at 8am and 8 pm. It may be taken on an empty stomach or with food to reduce stomach irritation. Your doctor may have you spread out your dosing to 3 or 4 times a day if you have trouble with nausea or diarrhea on a twice a day schedule. Do not make this change on your own or stop taking mycophenolate without first discussing it with your doctor. The most important thing to remember is to take it the same way everyday, either with or without food as the food can affect absorption. The capsules should be swallowed whole and not opened, crushed or chewed, the tablets should not be crushed or chewed either. If you can not swallow the capsule contact your prescriber about changing your Cellcept to a liquid form. Store capsules, tablets and liquid formulation at room temperature in a tightly closed container out of the reach of children.

What do I do if I a missed a dose or I have a late clinic appointment?

We do not routinely monitor mycophenolate levels so you do not have to hold your dose before clinic visits. If you miss a dose you can take it as soon as you remember, just try to separate doses by at least 6 hours.

Does mycophenolate interact with any foods or beverages?

No it does not. However you will likely also be taking tacrolimus, cyclosporine or sirolimus and you have to avoid the food and beverages that interact with those medications.

Does mycophenolate interact with other drugs?

Drug interactions can occur when one drug effects the levels of another drug, it can cause the levels to either go up or down. Always check with your transplant team before starting any new medications.

Please direct your medication questions to your transplant coordinator or transplant pharmacist.



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Interactions with mycophenolate may occur with the following:

Aluminum or magnesium containing antacids (Maalox®, Mylanta®)

• Separate administration by at least 2 hours before or after taking Cellcept®

Iron

• Separate administration by at least 2 hours before or after taking Cellcept®

Cholestyramine (Questran) or psyllium (Metamucil)

• Separate administration by at least 4 hours before or after taking Cellcept®

Birth control pills

• Cellcept® may decrease the effectiveness of birth control pills, if you are sexually active you <u>must</u> <u>use an additional method of birth control in addition to birth control pills</u> while taking Cellcept®.

What if I become pregnant, or are considering pregnancy or breast-feeding?

Some drugs are avoided during pregnancy due to the potential harm they may have on the unborn baby. The FDA has a grading system that lets you know how safe a drug is for your unborn child. It ranks drugs from A, where medical studies show no evidence for danger to the fetus or mother, to B, C, D and X, where the medical evidence indicates that the risk to the fetus outweighs any benefit to the mother. Mycophenolate was recently changed from a category C to a category D based on new information about infants born with birth defects. If you become pregnant while taking Cellcept® do not stop taking Cellcept. Call your doctor right away.

Important information for female patients of childbearing potential:

- You should have a negative pregnancy test within one week of starting Cellcept®.
- Taking MMF or MPA early in your pregnancy can increase your chance of miscarriage and increase the chance that your baby will have serious birth defects.
- Tell your doctor if you are planning a pregnancy and are using MMF (CellCept®) or MPA(Myfortic®). Based on your health, your doctor will decide which medicines are best for you during pregnancy and while you are trying to get pregnant.
- You must use **TWO** forms effective birth control if you are taking MMF or MPA, unless you choose abstinence as your only form of birth control.
- You must start using **TWO** forms of birth control four weeks before you begin taking MMF or MPA and continue until six weeks after you stop taking the medicine.

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Are there other precautions that I need to be concerned about while taking mycophenolate mofetil?

When you take medications that suppress your immune system you are at an increased risk of infection. Report promptly to your physician any indication of infection such as fever, sore throat, swollen glands, sores or lumps in the skin, abnormal bleeding or bruising. Avoid friends and family member that are sick, ask them to wear a mask in your presence. Avoid live vaccines while taking this drug and avoid contact with individuals who have recently taken the oral poliovirus vaccine or the live (nasal) seasonal or H1N1 flu vaccine. Be sure to inform your physician if you have had a recent infection, especially chicken pox or shingles. Long term use of immunosuppressive medications may place you at a higher risk of developing certain types of cancers such as skin cancer, cervical cancer and lymphoma (lymph node cancer). Therefore, contact your doctor if you develop symptoms such as a brown or black skin lesion with uneven borders, lymph node swelling or a change in the size and color of a mole. Patients taking mycophenolate mofetil should also remember to limit their time exposed to sunlight, tanning beds or sunlamps and should always remember to use sunscreen with a high protection factor (SPF 50 and above).

How long will I have to take mycophenolate mofetil ?

You will likely be on this immunosuppressant or one similar to it for as long as your transplanted organ is functioning. Over time, there may be some changes to the types of immunosuppressants you will take. Make sure your transplant team is aware of any changes made to this medication by other doctors.

What kind of side effects could I have while taking mycophenolate mofetil ?

Side effects can occur with any drug, even over-the-counter medications. Some of these side effects are mild where as other can be more severe. Minor reactions may resolve on their own but if they persist, contact your physician. For major reactions, you should contact your physician immediately. For mycophenolate, the following are the observed side effects:

Minor:

- rash
- headache

Major:

- fever
- sore throat
- severe stomach pain
- nausea/vomiting
- diarrhea
- low white blood count
- low platelet count
- high blood pressure
- anemia
- burning with urination or urinary frequency

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