

DRUG INFORMATION: MYCOPHENOLATE: CELLCEPT

Posted 04/10/2008] FDA informed healthcare professionals that the Agency is investigating a potential association between the use of mycophenolate mofetil (CellCept) and mycophenolate sodium (Myfortic), medicines used to prevent organ rejection, and the development of progressive multifocal leukoencephalopathy (PML), a life-threatening disease. PML is a rare disorder that affects the central nervous system usually occurring in patients with immune systems suppressed by disease or medicines. FDA is reviewing data submitted by Roche, including postmarketing reports it has received of PML in patients who took mycophenolate mofetil or mycophenolate sodium, and the proposed revisions to the CellCept prescribing information. FDA has asked Novartis, the maker of Myfortic, for data on PML cases and to revise the Myfortic prescribing information to include the same information about PML included in the CellCept prescribing information. FDA anticipates it may take about 2 months to complete its review of the postmarketing reports and the proposed revisions to the prescribing information. As soon as the review is completed, FDA will communicate the conclusions and recommendations to the public.

Until further information is available, patients and healthcare professionals should be aware of the possibility of PML, such as localized neurologic signs and symptoms in the setting of a suppressed immune system, including during therapy with CellCept and Myfortic. For more information visit the FDA website at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#mycophenolate> and
http://www.fda.gov/cder/drug/early_comm/mycophenolate.htm.

Risk of birth defects caused by mycophenolate:

Mycophenolate must not be taken by patients who are pregnant or who may become pregnant. There is a high risk that mycophenolate will cause loss of the pregnancy or will cause the baby to be born with birth defects (problems that are present at birth).

You should not take mycophenolate if you are pregnant or if you may become pregnant. You must have a negative pregnancy test within 1 week of the start of your treatment with mycophenolate. You must use two acceptable forms of birth control together for 4 weeks before you begin to take mycophenolate, at all times during your treatment, and for 6 weeks after you stop taking mycophenolate. Your doctor will tell you which forms of birth control are acceptable. Mycophenolate may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, implants, and injections), so it is especially important to use a second form of birth control along with this type of contraceptive.

Call your doctor right away if you think you are pregnant or if you miss a menstrual period.

Other risks of taking mycophenolate:

Mycophenolate may decrease your ability to fight infection. Wash your hands often and avoid people who are sick while you are taking this medication. If you experience any of the following symptoms, call your doctor immediately: sore throat, fever, chills, cold sores, blisters, swollen glands, extreme tiredness, loss of appetite, tingling or burning in one part of the body, pain or burning during urination, frequent urination, wound or sore that is warm or won't heal, drainage from a skin wound, general weak or sick feeling; white patches in the mouth, and other signs of infection.

Mycophenolate may increase your risk of developing certain types of cancer, including lymphoma (a type of cancer that develops in the lymph system) and skin cancer. Tell your doctor if you or anyone in your family has or has ever had skin cancer. Plan to avoid unnecessary or prolonged exposure to real and artificial sunlight and light therapy and to wear protective clothing, sunglasses, and sunscreen. This will decrease your risk of developing skin cancer. Call your doctor if you experience any of the following symptoms: pain or swelling in the neck, groin, or armpits; a change in the appearance of a mole; skin changes; or sores that do not heal.

Talk to your doctor about the risks of taking mycophenolate.

Why is this medication prescribed?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Mycophenolate (Cellcept) is used with other medications to prevent transplant rejection (attack of the transplanted organ by the transplant recipient's immune system) in people who have received kidney, heart, and liver transplants. Mycophenolate (Myfortic) is used with other medications to prevent the body from rejecting kidney transplants. Mycophenolate is in a class of medications called immunosuppressive agents. It works by weakening the body's immune system so it will not attack and reject the transplanted organ.

How should this medicine be used?

Mycophenolate comes as a capsule, a tablet, a delayed-release tablet, and a suspension (liquid) to take by mouth. It is usually taken twice a day on an empty stomach (1 hour before or 2 hours after eating or drinking). Take mycophenolate at about the same times every day, and try to space your doses about 12 hours apart. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take mycophenolate exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

The medication in the delayed-release tablet is absorbed differently by the body than the medication in the tablet and capsule, so this product cannot be substituted for the others. Each time you have your prescription filled, make sure that you have received the right product. If you think you received the wrong medication, talk to your doctor and pharmacist right away.

Swallow the tablets, delayed-release tablets, and capsules whole; do not split, chew, or crush them. Do not open the capsules.

Do not mix mycophenolate suspension with any other medication.

Be careful not to spill the suspension or to splash it onto your skin. If you do get the suspension on your skin, wash the area well with soap and water. If you get the suspension in your eyes, wash with plain water. Use wet paper towels to wipe up any spills.

Mycophenolate prevents organ transplant rejection only as long as you are taking the medication. Continue to take mycophenolate even if you feel well. Do not stop taking mycophenolate without talking to your doctor.

Other uses for this medicine:

Mycophenolate is also used to treat Crohn's disease (a condition in which the body attacks the lining of the digestive tract, causing pain, diarrhea, weight loss, and fever). Talk to your doctor about the possible risks of using this medication for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Before taking mycophenolate,

- tell your doctor and pharmacist if you are allergic to mycophenolate, mycophenolic acid, or any other medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking. Be sure to mention any of the following: activated charcoal; acyclovir (Zovirax); antibiotics; azathioprine (Imuran); cholestyramine (Questran); colestipol (Colestid); ganciclovir (Cytovene); phenytoin (Dilantin); probenecid (Benemid); salicylate pain relievers such as aspirin, choline magnesium trisalicylate (Trisalate), choline salicylate (Arthropan), diflunisal (Dolobid), magnesium salicylate (Doan's, others) and salsalate (Argesic, Disalcid, Salgesic); theophylline (TheoDur); valacyclovir (Valtrex); and valganciclovir (Valcyte). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- if you are taking antacids, take them 2 hours before or 4 hours after you take mycophenolate.
- tell your doctor if you have or have ever had Lesch-Nyhan syndrome or Keeley-Seegmiller syndrome (inherited diseases that cause high levels of a certain substance in the blood, joint pain, and problems with motion and behavior); ulcers or any disease that affects your stomach, intestines, or digestive system; any type of cancer; or liver or kidney disease.
- tell your doctor if you are breast-feeding.
- do not have any vaccinations without talking to your doctor.
- ask your doctor if you should get a flu vaccine before or during your treatment because taking mycophenolate increases your risk of infection.
- if you have phenylketonuria (PKU, a inherited condition in which a special diet must be followed to prevent mental retardation), you should know that mycophenolate suspension may be sweetened with aspartame, a source of phenylalanine.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Pending revision, the material in this section should be considered in light of more recently available information in the MedWatch notification at the beginning of this monograph.

Mycophenolate may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- diarrhea
- constipation
- stomach pain
- nausea
- vomiting
- difficulty falling asleep or staying asleep
- pain, especially in the back, muscles, or joints
- uncontrollable shaking of a part of the body
- headache
- dizziness
- rash

Some side effects can be serious. If you experience any of the following symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- swelling of the hands, arms, feet, ankles, or lower legs
- difficulty breathing
- unusual bruising or bleeding
- chest pain
- fast heartbeat
- excessive tiredness
- pale skin
- weakness
- black and tarry stools
- red blood in stools
- bloody vomit
- vomiting material that looks like coffee grounds
- loss of muscle tone

Mycophenolate may cause other side effects. Call your doctor if you have any unusual problems while taking this medication. If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online <http://www.fda.gov/MedWatch/index.html> or by phone 1-800-332-1088.

Symptoms of overdose may include:

- stomach pain
- nausea
- vomiting
- diarrhea
- fever, chills, and other signs of infection

Excerpted from <http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a601081.html>