



Myfortic (mycophenolic acid)

Audience: Renal, cardiac, and hepatic transplantation healthcare professionals

[Posted 09/03/2009] Novartis and FDA notified healthcare professionals that cases of Pure Red Cell Aplasia (PRCA) have been reported in patients treated with Myfortic. The WARNINGS and ADVERSE REACTIONS sections of the Myfortic Prescribing Information have been revised to reflect this new safety information.

PRCA is a type of anemia in which there is a selective reduction of red blood cell precursors on bone marrow examination. Patients with PRCA may present with fatigue, lethargy, and/or abnormal paleness of the skin (pallor). In some cases, PRCA was found to be reversible with dose reduction or cessation of Myfortic therapy. In transplant patients, however, reduced immunosuppression may place the graft at risk.

Novartis Pharmaceuticals Corporation would like to inform you that new postmarketing safety information has been added to the **WARNINGS** and **ADVERSE REACTIONS** sections of the *myfortic* Prescribing Information. Cases of pure red cell aplasia (PRCA) have been reported in patients treated with mycophenolate mofetil (MMF) in combination with other immunosuppressive agents. MMF is converted to mycophenolic acid (MPA), the active ingredient in *myfortic*, following oral or IV administration.

The new important safety information in the *myfortic* Prescribing Information includes: **“WARNINGS (SEE BOXED WARNING) Pure Red Cell Aplasia.** Cases of pure red cell aplasia (PRCA) have been reported in patients treated with mycophenolate mofetil (MMF) in combination with other immunosuppressive agents. MMF is metabolized to mycophenolic acid (MPA), the active ingredient in Myfortic and the active form of the drug. The mechanism for MMF induced PRCA is unknown; the relative contribution of other immunosuppressants and their combinations in an immunosuppressive regimen are also unknown. In some cases PRCA was found to be reversible with dose reduction or cessation of MMF therapy.

In transplant patients, however, reduced immunosuppression may place the graft at risk. Changes to Myfortic therapy should only be undertaken under appropriate supervision in transplant recipients in order to minimize the risk of graft rejection (see ADVERSE REACTIONS, Postmarketing Experience).

The complete revised Prescribing Information and Medication Guide can be found on the Internet at <http://www.myfortic.com>. Contact Novartis if you have any questions about this information or the safe and effective use of *myfortic*.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of *myfortic* to Novartis Pharmaceuticals Corporation, One Health Plaza, East Hanover, NJ 07936 or by phone at 1-888-NOW-NOVA (1-888-669-6682), Monday through Friday from 8:30 AM - 5:00 PM EST

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