

PVC Drug Safety Communication: FDA Approves a Single Shared Risk Evaluation and Mitigation Strategy (REMS) for Mycophenolate-containing Medicines
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Pharmacy, Patient Safety and Provider community: Please share with pharmacists and providers at your MTFs and regions.

The FDA has approved a single, shared system Risk Evaluation and Mitigation Strategy (REMS) for all Mycophenolate-containing prescription medicines. The drug 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 a transplanted organ.

A REMS is a risk management plan that goes beyond requirements in the drug prescribing information to manage serious risks associated with a drug. Under the Food and Drug Administration Amendments Act of 2007, FDA has the authority to require a manufacturer to develop a REMS when further measures are needed to ensure that the drug's benefits outweigh its risks.

Mycophenolate-containing medicines are associated with an increased risk of first trimester pregnancy loss (miscarriage) and congenital malformation (birth defects) if taken during pregnancy. To prevent unplanned pregnancies in patients using Mycophenolate-containing medicines and to minimize fetal exposure to Mycophenolate, FDA and the Mycophenolate product manufacturers developed a single, shared system called the "Mycophenolate REMS." The Mycophenolate REMS includes a Medication Guide, training for health care professionals, and the establishment of a pregnancy registry for women who become pregnant and agree to participate in the registry.

MYCOPHENOLATE USE IN DOD: A Pharmacovigilance Center (PVC) analysis of MHS data showed there were 751 and 739 females aged 14 to 45 years with one or more prescription for mycophenolate in FY11 and FY12, respectively. Although the information should be provided to every mycophenolate user, women of child bearing age are most likely to benefit from the REMS information.

Complete information can be found at: www.MycophenolateREMS.com

Information about the pregnancy registry is available at:
www.MycophenolatePregnancyRegistry.com

Additional information, including answers to questions related to the Mycophenolate-containing Medicines REMS, can be found at the following website link:
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm318880.htm>

Information on MedWatch: <http://www.fda.gov/Safety/MedWatch/default.htm>

QUESTIONS OR ADDITIONAL INFORMATION: Send requests for additional information regarding this alert or the analysis conducted by the Pharmacovigilance Center (PVC) to: otsg.pvc@amedd.army.mil