# FDA issues Myfortic tablets safety alert

November 28 2007

The U.S. Food and Drug Administration issued a safety alert for pregnant patients using the kidney transplant drug Myfortic delayed-release tablets.

The FDA said it has been determined the medication is associated with increased risks of pregnancy loss and congenital malformations. Officials said the pregnancy category for Myfortic has been changed to Category D -- positive evidence of fetal risk.

Myfortic is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants, administered in combination with cyclosporine and corticosteroids.

The FDA said a transplant patient planning a pregnancy shouldn't use Myfortic unless she cannot be successfully treated with other immunosuppressant drugs.

Myfortic is manufactured by Novartis Pharmaceuticals.