Cefepime:Label Change- Risk of Seizure in Patients Not Receiving Dosage Adjustments for Kidney Impairment

U.S. Food & Drug Administration

Audience: Health Professional,Infectious Disease, Nephrology

Issue: There have been cases of a specific type of seizure called nonconvulsive status epilepticus associated with the use of cefepime, primarily in patients with renal impairment who did not receive appropriate dosage adjustments of cefepime. The Warnings and Precautions and Adverse Reactions sections of the cefepime label are being revised to highlight this risk.

Background:Cases of nonconvulsive status epilepticus associated with cefepime are documented in the medical literature and have been identified in FDA's Adverse Event Reporting System (AERS) database. Most cases occurred in patients with renal impairment who did not receive appropriate dosage adjustment; however, some cases occurred in patients receiving dosage adjustment appropriate for their degree of renal impairment. In the majority of cases, the seizures were reversible and resolved after discontinuing cefepime and/or after hemodialysis. See the Drug Safety Communication for additional information.

Recommendations: Health care professionals should adjust the dosage of cefepime in patients with creatinine clearance less than or equal to 60 mL/min. If seizures associated with cefepime therapy occur, consider discontinuing cefepime or making appropriate dosage adjustments in patients with renal impairment.

Caregivers who notice symptoms of nonconvulsive status epilepticus in a patient receiving cefepime should seek medical attention right away. Symptoms of nonconvulsive status epilepticus could include altered mental status, confusion, and decreased responsiveness.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[06/26/2012 - Drug Safety Communication [3] - FDA]

SOURCE [4]

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http://www.mdtmag.com/news/2012/06/cefepimelabel-change-risk-seizure-patients-not-receiving-dosage-adjustments-kidney-impairment

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/ucm309661.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm309822.htm