



U.S. Food & Drug Administration

Drugs



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FDA Drug Safety Communication: Cefepime and risk of seizure in patients not receiving dosage adjustments for kidney impairment

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Safety Announcement

[6-26-2012] The U.S. Food and Drug Administration (FDA) is reminding health care professionals about the need to adjust the dosage of the antibacterial drug cefepime in patients with renal (kidney) impairment. 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.

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 (see [Data Summary](#) below). 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.

To minimize the risk of seizures, health care professionals should adjust the dosage of cefepime in patients with creatinine clearance less than or equal to 60 mL/min (see [product label](#)¹). If seizures associated with cefepime therapy occur, consider discontinuing cefepime or making appropriate dosage adjustments in patients with renal impairment.

Additional Information for Patients and Caregivers

- Cefepime is generally administered to hospitalized patients, however, some patients may continue to receive cefepime at home after they have been discharged from the hospital.
- 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.
- Patients should contact their health care professional if they have any questions or concerns about cefepime.
- Patients and caregivers should report side effects from cefepime to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Additional Information for Health Care Professionals

- The dosage of cefepime should be adjusted in patients with creatinine clearance less than or equal to 60 mL/min.
- Nonconvulsive status epilepticus has been reported with cefepime. Most cases occurred in patients with renal impairment for whom the dosage was not appropriately adjusted.
- In the majority of cases, the seizures were reversible and resolved after discontinuation of cefepime and/or after hemodialysis. If a patient experiences a seizure during cefepime therapy, health care professionals should consider discontinuing cefepime or making appropriate dosage adjustments in patients with renal impairment.
- Health care professionals should report adverse events involving cefepime to the FDA MedWatch program using the information in the "Contact FDA" box at the bottom of this page.

Data Summary

A search of FDA's Adverse Event Reporting System (AERS) database, from the approval of cefepime, in 1996, through February 2012, identified 59 cases of nonconvulsive status epilepticus during cefepime administration; 56% of these cases involved patients >65 years of age (range: 7-95 years) and 69% of the 59 cases involved female patients. Renal dysfunction was present in 58/59 patients (renal status was unknown in one patient). In 56/59 patients, cefepime dosing was not appropriately adjusted for renal impairment as recommended in the cefepime label. Nonconvulsive status epilepticus resolved in 43 patients. Of the 16 patients who died, 13 deaths were caused by intercurrent illness (another illness that developed at the same time). Of the remaining three deaths, one involved a patient with central nervous system disease and a ventriculoperitoneal shunt who had ongoing seizure activity after discontinuing cefepime. The second death occurred in a patient who had concomitantly elevated amoxicillin levels possibly contributing to seizures, and insufficient data prevented determination of the cause of the third death.

FDA also reviewed case reports and case series in the medical literature. In general, patients who developed signs of neurotoxicity with cefepime were 50 years of age or older, had underlying renal dysfunction, and often did not receive appropriate dosage adjustments. Some patients had underlying central nervous system pathology or prior history of seizures on other beta-lactam antibacterial drugs or cephalosporins.

Related Information

- [Information on Cefepime \(marketed as Maxipime\)](#)²
- [Cefepime Label](#)³
- [FDA Drug Safety Podcast for Healthcare Professionals: Cefepime and risk of seizure in patients not receiving dosage adjustments for kidney impairment](#)⁴

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