

## SPINE SAFETY NOTICE:

### **Information for Healthcare Professionals:**

Rocephin® (ceftriaxone sodium) for injection –

### **Potential Risk Associated With Concomitant Use Of Rocephin With Calcium Containing Products**

According to Medwatch, Roche informed healthcare professionals about revisions made to the prescribing information for Rocephin® to clarify the potential risk associated with concomitant use of Rocephin® with calcium or calcium-containing solutions or products.

Healthcare professionals are advised that Rocephin® and calcium-containing solutions including continuous calcium-containing infusions such as parenteral nutrition, should not be mixed or co-administered to any patient irrespective of age, even via different infusion lines at different sites. Rocephin® and IV calcium-containing solutions should not be administered within 48 hours of each other in any patient. No data are available on the potential interaction between ceftriaxone and oral calcium-containing products or interaction between intramuscular ceftriaxone and calcium-containing products (IV or oral).

The complete MedWatch Safety Summary, including a link to the Dear Healthcare Professional Letter, Prescribing information, and the Healthcare Professional Sheet regarding this issue, are available at:

<http://www.fda.gov/medwatch/safety/2007/safety07.htm#Rocephin>

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### **Important Revisions to the Prescribing Information**

*Clostridium difficile* associated diarrhea

According to MedWatch, modifications have been made to the WARNINGS and PRECAUTIONS sections of Rocephin® labeling. The revised WARNINGS and PRECAUTIONS sections now address *Clostridium difficile* associated diarrhea (CDAD) and provides information for patients related to the importance of contacting their physicians.

*Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Rocephin®, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. *C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these

infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

The complete MedWatch Safety Labeling Changes, including links to prescribing information, are available at:

<http://www.fda.gov/medwatch/SAFETY/2007/jul07.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS Web site at [http://www.spine.org/spine\\_safety\\_notices.cfm](http://www.spine.org/spine_safety_notices.cfm). This information is provided as a service for information and education only.