June 2007

IMPORTANT PRESCRIBING INFORMATION

Dear Healthcare Professional:

Roche would like to advise you of a recent update to the Rocephin® (ceftriaxone sodium) for Injection prescribing information that provides new information in the CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and DOSAGE AND ADMINISTRATION sections describing the potential risk associated with concomitant use of Rocephin with calcium or calcium-containing solutions or products. This revision to the prescribing information is a result of information about adverse events reported during postmarketing clinical use of Rocephin. In addition, consistent with information currently in the Pediatric Use subsection of the prescribing information, new text has been added in the CONTRAINDICATIONS section to more prominently reinforce that hyperbilirubinemic neonates, especially prematures, should not be treated with Rocephin.

The Rocephin prescribing information contains specific information in the DOSAGE AND ADMINISTRATION: *COMPATIBILITY AND STABILITY* section on how ceftriaxone should be reconstituted. **Calcium-containing solutions are not among the appropriate solutions described for reconstitution, due to possible incompatibility.**

In the past few years, however, isolated neonatal deaths associated with calcium-ceftriaxone precipitates in the lungs and kidneys have been described worldwide. In some of these cases ceftriaxone and the calcium-containing solutions or medications were administered by different routes and at different times.

Accordingly, new information has been added to the Rocephin prescribing information in the CONTRAINDICATIONS section as follows:

Hyperbilirubinemic neonates, especially prematures, should not be treated with Rocephin. In vitro studies have shown that ceftriaxone can displace bilirubin from its binding to serum albumin and bilirubin encephalopathy can possibly develop in these patients.

Rocephin should not be administered concurrently with calcium-containing solutions or products in newborns because of the risk of precipitation of ceftriaxone-calcium salt (see **WARNINGS**).

New information has been added to the prescribing information in the WARNINGS section in bold font as new paragraphs, as follows:

Ceftriaxone must not be mixed or administered simultaneously with calcium-containing solutions or products, even via different infusion lines.

Calcium-containing solutions or products must not be administered within 48 hours of last administration of ceftriaxone.

Cases of fatal reactions with calcium-ceftriaxone precipitates in lung and kidneys in both term and premature neonates have been described. In some cases the infusion lines and times of administration of ceftriaxone and calcium-containing solutions differed (see CONTRAINDICATIONS and ADVERSE REACTIONS).

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New information has also been added to the prescribing information in the DOSAGE AND ADMINISTRATION: *DIRECTIONS FOR USE* and *COMPATIBILITY AND STABILITY* sections in bold font, as follows:

Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution, to reconstitute Rocephin. Particulate formation can result.

The updates in the PRECAUTIONS and ADVERSE REACTIONS sections of the prescribing information reflect the changes as described above.

Updated prescribing information is enclosed for your information. In addition, healthcare professionals can access the revised Rocephin prescribing information at http://www.rocheusa.com/products/rocephin.

We encourage you to become familiar with these changes in the prescribing information. If you have any questions or require additional information concerning Rocephin, please contact the Roche Pharmaceuticals Service Center at 1-800-526-6367.

Roche will continue to monitor the safety of Rocephin through established reporting mechanisms and notify regulatory authorities of any serious adverse events for evaluation. We will continue to provide you with the most current prescribing information for Rocephin moving forward. You can assist us in monitoring the safety of Rocephin by reporting adverse reactions to us at 1-800-526-6367 or by FAX at 1-800-532-3931; or to the FDA at www.fda.gov/medwatch or by mail to MedWatch, HF-2, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20851.

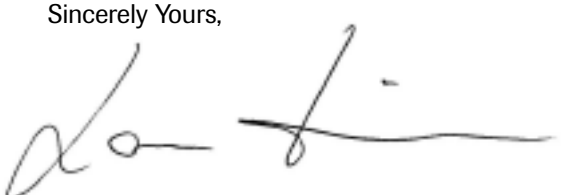
Safety Information

Rocephin is indicated for the treatment of lower respiratory tract infections, urinary tract infections, bacterial septicemia, skin/skin structure infections, bone and joint infections, pelvic inflammatory disease, uncomplicated gonorrhea, intra-abdominal infections, acute bacterial otitis media and meningitis when caused by susceptible organisms (please see the Prescribing Information for a list of susceptible organisms). Rocephin is also indicated for surgical prophylaxis in patients undergoing certain surgical procedures (please see the Prescribing Information for a description of these surgical procedures).

Adverse clinical effects in adults occur at levels similar to those of other cephalosporins: diarrhea (2.7%), rash (1.7%) and local reactions (≤1%). Rocephin is contraindicated in patients with a known allergy to cephalosporins and should be used cautiously in penicillin-sensitive patients.

Hyperbilirubinemic neonates, especially prematures, should not be treated with Rocephin. Rocephin should not be administered concurrently with calcium-containing solutions or products in newborns because of the risk of precipitation of ceftriaxone-calcium salt. Ceftriaxone must not be mixed or administered simultaneously with calcium-containing solutions or products, even via different infusion lines.

Sincerely Yours,



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Enclosure: Prescribing Information for Rocephin® (ceftriaxone sodium) for Injection