

## Pharmacovigilance e-shot from the Department of Pharmacovigilance

### Ceftriaxone

#### Updated recommendations concerning the interaction with calcium-containing products

USA: The United States Food and Drugs Authority (US FDA) has notified health-care professionals of an update to an earlier alert (September 2007) that addresses the interaction of Ceftriaxone (a broad-spectrum cephalosporin antibiotic marketed as Rocephin® and generics) with calcium-containing products, based on previously reported fatal cases in neonates. The manufacturer of ceftriaxone conducted two *in vitro* studies using neonatal and adult plasma to assess the potential for precipitation of ceftriaxone-calcium when ceftriaxone and calcium-containing products are mixed in vials and in infusion lines. Based on the results from these studies, the US FDA has recommended the following:

- Concomitant use of ceftriaxone and intravenous calcium-containing products is contraindicated in neonates (28 days of age and under). Ceftriaxone should not be used in neonates (28 days of age and under) if they are receiving (or are expected to receive) calcium-containing products.
- In patients aged above 28 days, ceftriaxone and calcium-containing products may be administered sequentially, provided the infusion lines are thoroughly flushed between infusions with a compatible fluid.
- Ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions via a Y-site in any age group.
- Ceftriaxone and calcium-containing products may be used concomitantly in patients aged over 28 days, using the precautionary steps above because the risk of precipitation is low in this population. The US FDA had previously recommended, but no longer recommends, that in all age groups, ceftriaxone and calcium-containing products should not be administered within 48 hours of one another.

#### Reference:

Information for Healthcare Professionals, US FDA, 21 April 2009 ([www.fda.gov](http://www.fda.gov))  
WHO Pharmaceuticals Newsletter No. 3, 2009. Pg 1-2

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