



SFDA SAFETY COMMUNICATION

Serious Interaction of ceftriaxone with Calcium-containing Products

The Saudi Food & Drug Authority (SFDA) would like to highlight a medication safety hazard concerning concomitant use of parenteral calcium-containing products with ceftriaxone. This communication issued to all practicing healthcare professionals (HCPs) and decision makers at concerned institutions based some reports addressing such a hazardous interaction.

The National Pharmacovigilance and Drug Safety Center (NPC) has received a couple of local cases associated with life threatening adverse event resulted from reconstitution of Ceftriaxone with Ringer lactate or other calcium-containing solvents.

Therefore, the SFDA emphasizes that HCPs must not reconstitute or mix ceftriaxone with calcium-containing products, such as Ringer lactate or Hartmann's solution or parenteral nutrition containing calcium. This will lead to formation of crystalline materials which may precipitate in the intravenous tubing and ends in a catastrophic vein closures in patients' kidneys and/or lungs, even via different infusion lines at different sites.

According to the product information leaflet, ceftriaxone is stable for 24 hours at room temperature only in 0.9% sodium chloride, sodium chloride 0.45% + glucose 2.5%, hydroxyethyl starch 6-10%, water for injection, or 5% dextrose in water (D5W).

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to report ADRs resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)

Saudi Food and Drug Authority-Drug sector

3292 Northern Ring Road

Al Nafal District

Riyadh 13312 – 6288

Kingdom of Saudi Arabia

Toll free number: 8002490000

Tel: 19999

Fax: 012057662

Email: NPC.Drug@sfda.gov.sa