SFDA SAFTEY COMMUNICATION

Mar 21th, 2012

Saudi Food and Drug Authority (SFDA) PRESS RELEASE – Important Safety Information on Dilution of Ranitidine Intravenous Injection

The Saudi Food and Drug Authority (SFDA) would like to provide healthcare professionals with an important safety information concerning dilution of ranitidine 50 mg/2 ml intravenous injection. The SFDA has received several reports of death cases occurred after the administration of undiluted intravenous ranitidine 50 mg/2 ml injection. Therefore, SFDA would like to remind healthcare professionals regarding the proper technique of diluting and administrating ranitidine 50 mg/2ml intravenously. Full information on ideal dilution technique is highlighted in the Product Package Insert and summarized in the following table:

	Method of Administration	**Dilution Procedure**
1	Intermittent intravenous bolus	Dilute ranitidine 50 mg/2ml in 0.9% sodium chloride solution or other compatible IV solution to a concentration no greater than 2.5 mg/mL (20 mL). Inject at a rate no greater than 4 mL/min (over 5 minutes) every 6-8 hours.
2	Intermittent intravenous infusion	Dilute ranitidine 50 mg/2ml in 5% dextrose solution (D5W) or other compatible IV solution to a concentration no greater than 0.5 mg/mL (100 mL). Infuse at a rate no greater than 5 to 7 mL/min (over 15 to 20 minutes) every 6-8 hours.

3	Continuous intravenous infusion	Dilute ranitidine 50 mg/2ml, in 5% dextrose solution (D5W) or other compatible IV solution to a concentration of 0.625 mg/mL. Infuse at a rate of 10.7 mL/hour. For Zollinger-Ellison patients, dilute ranitidine 50mg/2ml in 5% dextrose solution (D5W) or other compatible IV solution to a concentration no greater than 2.5 mg/mL. Start infusion at a rate of 1.0 mg/kg/hour, the dose should be adjusted upward in 0.5mg/kg/hour increments according to the clinical status of the patient. Dosages up to 2.5 mg/kg/hour and infusion rates as high as 220 mg/hour have been used.

Report Adverse Drug Events (ADEs) to the SFDA

The SFDA urges both healthcare professionals and patients to report ADEs resulted from using such a medication and other 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: 01 2038222 ext. 2317, 2353, 2356, 2340, 5769
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa