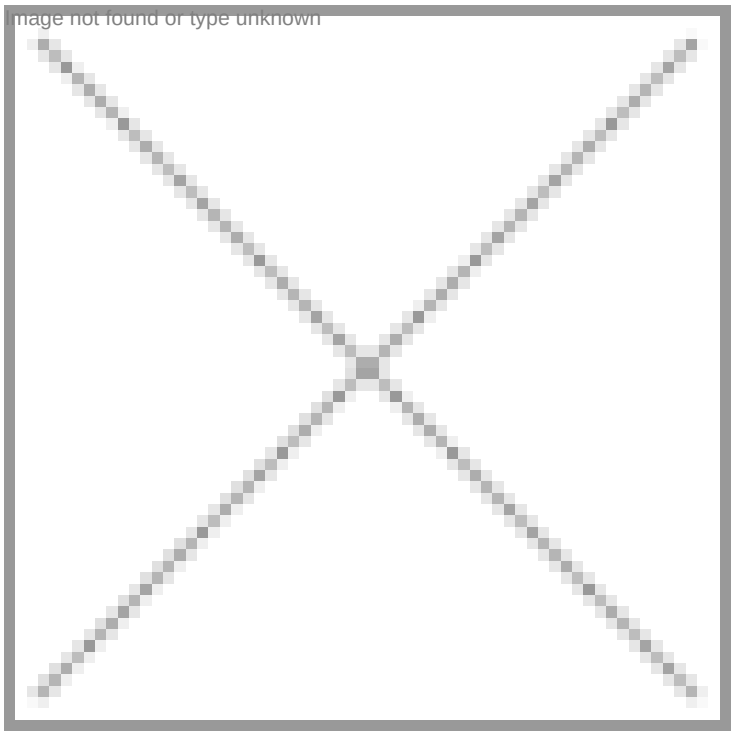
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Baxter recalls nitroglycerin in 5% Dextrose Injection in US

29 November 2013 | News | By BioSpectrum Bureau



Singapore: Baxter International has initiated a voluntary recall of one lot of Nitroglycerin in 5 percent Dextrose Injection due to particulate matter found in one vial. If infused, particulate matter could lead to potential venous and/or arterial thromboembolism (blockage of blood vessels).

Other adverse events associated with injection of particulate matter include inflammation due to foreign material, particularly in the lungs, and local irritation of blood vessels.

There have been no reported adverse events associated with this issue to date. The financial impact of this recall is not material to Baxter.

Nitroglycerin in 5 percent Dextrose Injection (Intravenous) is indicated for treatment of peri-operative hypertension (treatment of high blood pressure before, during and after surgery); for control of congestive heart failure in the setting of acute myocardial infarction (during a new onset heart attack, a weakness of the heart muscle may cause fluid to build up in the lungs and other body tissues); for treatment of angina pectoris (chest pain) in patients who have not responded to sublingual nitroglycerin and Î²-blockers (beta blocker drugs); and for induction of intraoperative hypotension (low blood pressure during surgery).

Baxter's Nitroglycerin in 5 percent Dextrose Injection is packaged in 250 mL glass containers, with 12 glass containers per carton. The affected product code is 1A0694, and the affected lot number is G105197. Product affected by this recall was distributed to healthcare centers and distributors in Colombia, Saudi Arabia and the United States.