

American Regent Initiates Nationwide Voluntary Recall of Caffeine & Sodium Benzoate Injection, USP 250 mg/mL, 2 mL Single Dose Vial Due to Visible Particulates

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SHIRLEY, N.Y., May 5, 2011 /PRNewswire/ -- American Regent is conducting a nationwide voluntary recall to the consumer and user level of the following product:

**Caffeine & Sodium Benzoate Injection, USP, 250 mg/mL, 2 mL Single Dose Vial,
NDC # 0517-2502-10, Lot # 0084, Exp Date February, 2012**

PLEASE NOTE: This recall, initiated on May 5, 2011 to the User or Consumer Level, is for Lot # 0084 Only. No other lots of Caffeine & Sodium Benzoate Injection, USP are subject to this voluntary recall.

This voluntary recall was initiated because some of the vials of this lot may contain visible particulates. Potential adverse events after intravenous administration of solutions containing particulates may include disruption of blood flow within small blood vessels in the lung, localized inflammation (swelling and redness), and granuloma formation. Intramuscular administration could result in foreign body inflammatory response, with local pain, swelling and possible long term granuloma formation. American Regent is undertaking this voluntary recall in consideration of the potential for safety issues, if this lot of Caffeine & Sodium Benzoate Injection, USP is administered to patients.

Caffeine and Sodium Benzoate Injection has been used in conjunction with supportive measure to treat respiratory depression associated with overdose with CNS depressant drugs (e.g., narcotic analgesics, alcohol). However, because of questionable benefit and transient action, most authorities believe caffeine and other analeptics should not be used in these conditions and recommend other supportive therapy.

The product was distributed to wholesalers and distributors nationwide.

Hospitals, Emergency Rooms, Clinics and other healthcare facilities should not use American Regent Inc., Caffeine & Sodium Benzoate Injection, USP, 250 mg/mL, 2 mL Single Dose Vials with Lot # 0084 fo

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[SOURCE](#) [1]

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http://www.mdtmag.com/news/2011/05/american-regent-initiates-nationwide-voluntary-recall-caffeine-sodium-benzoate-injection-usp-250-mg/ml-2-ml-single-dose-vial-due-visible-particulates?qt-recent_content=0

Links:

[1] <http://www.bio-medicine.org/medicine-technology-1/American-Regent-Initiates-Nationwide-Voluntary-Recall-of-Caffeine--26amp-3B-Sodium-Benzoate-Injection--USP-250-mg-mL--2-mL-Single-Dose-Vial-Due-to-Vis-17008-1/>