AMERICAN REGENT®

IMPORTANT DRUG ADMINISTRATION INFORMATION

READ PRIOR TO USE OF THIS PRODUCT

Caffeine and Sodium Benzoate Injection, USP, 250 mg/mL (125 mg/mL Caffeine)
2 mL Single Dose Vials
NDC# 0517-2502-10

July 18, 2016

All lots of Caffeine and Sodium Benzoate Injection, USP, 250 mg/mL, 2 mL Single Dose Vials, manufactured by Luitpold Pharmaceuticals, Inc. (distributed by American Regent, Inc.) in commercial distribution may exhibit evidence of visible or sub-visible particles.

Internal procedures are in place to detect visible particles that may be present in Caffeine and Sodium Benzoate Injection, USP, prior to release. Each lot is 100% inspected by automated inspection machinery that is designed to detect visible particles. In addition to automated inspection, samples of filled product are visually examined by Quality Assurance as part of normal lot release procedures. All lots that have been released for distribution have been inspected in this manner, and have met all release specifications for particulates. However, there is a potential for the transient appearance of particles that represent trace amounts of the product's active ingredient.

As a precautionary measure, a filter must be used for the withdrawal and administration of all lots of Caffeine and Sodium Benzoate Injection, USP.

The following procedure must be used for the admixture and administration of all lots of Caffeine and Sodium Benzoate Injection, USP.

1. Perform a visual inspection of the vial prior to withdrawal of the contents.

   DO NOT USE IF PARTICULATES ARE PRESENT. USE A NEW VIAL.

2. Use a 5 micron filter needle to withdraw the required calculated volume of Caffeine and Sodium Benzoate Injection, USP, from the 2 mL Single Dose Vial(s).

3. If the product is to be administered intramuscularly, withdraw contents of Caffeine and Sodium Benzoate Injection, USP, with a 5 micron filter needle and appropriate syringe. Remove the filter needle from the syringe and replace with an appropriate needle for injection before administration.

4. If the product is to be administered by direct intravenous injection or as part of an infusion solution, remove the filter needle and attach a standard needle (if applicable) to the syringe prior to patient administration or before adding to a larger volume of intravenous fluid.

   NOTE: Aseptic addition of Caffeine and Sodium Benzoate Injection, USP, to infusion solutions under a laminar flow hood is recommended.

   Visually inspect the final intravenous injection or intravenous admixture solution.

   DO NOT USE IF PRECIPITATE or PARTICULATES ARE VISIBLE. DISCARD. USE A NEW VIAL AND REPEAT ABOVE PROCEDURES.

5. Use a 0.22 micron in-line filter when administering the final direct intravenous injection or intravenous admixture to patients.

If particulates are observed, or if you require additional information, please contact the Medical Affairs Department at 1-877-788-3232 (Monday - Friday: 9:00 am - 5:00 pm ET) or e-mail at: inquiry@americanregent.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting Program online, by regular mail, telephone or by fax.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form
- **Telephone**: 1-800-FDA-1088
- **Fax:** 1-800-FDA-0178

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