

October 19, 2009

Dexferrum (iron dextran injection) - Labeling Change

American Regent and FDA notified healthcare professionals that anaphylactic-type reactions, including fatalities, have followed the parenteral administration of iron dextran injection.

The Boxed Warning has been modified to recommend administering a test dose prior to the first therapeutic dose and observing for signs or symptoms of anaphylactic-type reactions during administration of Dexferrum.

Fatal reactions have followed the test dose of iron dextran injection, even in situations where the test dose was tolerated. Patients with a history of drug allergy or multiple drug allergies may be at increased risk of anaphylactic-type reactions. It is recommended that resuscitation equipment and personnel trained in the detection and treatment of anaphylactic-type reactions be readily available during Dexferrum administration.

Prescribers are encouraged to review the full prescribing information and discuss it with their patients in order to make the appropriate treatment decisions based on the benefit-risk profile of iron dextran products.

A copy of the revised full prescribing information is enclosed and available on American Regent's website at www.americanregent.com, or call Professional Services Department at 1-800-645-1706.

Healthcare professionals should report all serious adverse events that may be suspected to be associated with the use of Dexferrum® to

Luitpold Pharmaceuticals, Inc.
800 Adams Avenue, First Floor
Valley Forge, Pennsylvania, 19403

Or by phone at 1-800-734-9236, Monday through Friday from 9:00 AM - 5:00 PM eastern time.

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