



JHP Pharmaceuticals Introduces a Dantrium® IV

(dantrolene sodium for injection), rapidly mixing at 20 seconds

PARSIPPANY, NJ SEPTEMBER 28 2009

JHP Pharmaceuticals, LLC (“JHP”) announced today that it had developed, and received approval by the FDA for Dantrium® IV (*dantrolene sodium for injection*), a rapidly mixing product. Dantrium® IV now reconstitutes in approximately 20 seconds, which is 4 times faster than before, saving valuable time and effort during a malignant hyperthermia (MH) emergency.

Dantrium® IV, the rapidly mixing product, has the following essential benefits

- Reconstitutes in approximately 20 seconds with noticeably less vigorous shaking required to complete the reconstitution process
- Easier and faster introduction of diluent into the Dantrium® IV vial

JHP has also introduced two new features in the Dantrium® IV vial; an easy-to-open flip-off vial cap and an easy-to-identify red vial cap and red vial label.

Stuart Hinchey, co-founder and President of JHP said “We are excited about the dramatic enhancements we have been able to make to Dantrium® IV. The stunning improvement in reconstitution time represents breakthrough innovation that significantly heightens the life-saving characteristics of a drug 30 years after its successful introduction. During fulminant MH, when a patient’s core temperature can increase by as much 1° Centigrade every 5 minutes¹ and time is obviously a crucial factor, Dantrium® IV can now be reconstituted 4 times faster than before. Taking into account the 36 vials that are recommended by MHAUS (Malignant Hyperthermia Association of the United States) and often needed to stabilize a patient with MH, Dantrium® IV, the rapidly mixing product, saves up to 36 minutes of mixing time.”

About Malignant Hyperthermia and Dantrium® IV (*dantrolene sodium for injection*)

Malignant hyperthermia (“MH”) is life threatening and manifests in susceptible individuals as a hypermetabolic response on exposure to halogenated volatile anesthetics and depolarizing muscle relaxants³. Most surgical facilities use MH triggering agents.

Since the introduction of Dantrium® IV, the mortality and morbidity rate associated with MH has plummeted from a high of 80% to less than 5%².

To order Dantrium® IV (*dantrolene sodium for injection*), the rapidly mixing product directly from JHP Pharmaceuticals, please call 1.877.547.4547 or Fax 1.866.923.4547.

Dantrium® IV is also available through your local distributor.

Dantrium® IV is indicated, along with supportive measures, for managing fulminant hypermetabolism of skeletal muscle characteristic of malignant hyperthermia crises in patients of all ages. Dantrium® IV is

also indicated preoperatively, and sometimes postoperatively, to prevent or attenuate the development of clinical and laboratory signs of MH in individuals judged to be MH susceptible.

Management of Malignant Hyperthermia (MH) crises requires various supportive measures individualized for the patient's condition. Administration of Dantrium® IV is one component of therapy and should not be considered a substitute for these measures. Even when properly treated, an MH crisis can result in death. Adverse events with Dantrium® IV include loss of grip strength, weakness in the legs, drowsiness, dizziness, thrombophlebitis, and tissue necrosis/injection site reactions secondary to extravasation. There have been rare reports of pulmonary edema, urticaria and erythema.

Please see accompanying full prescribing information for Dantrium® IV.

MHAUS (Malignant Hyperthermia Association of the United States) recommends keeping 36 vials of Dantrium® IV in a designated cart available for emergency use. Dantrium® IV has 36 months of shelf life.

About JHP Pharmaceuticals, LLC

JHP, headquartered in New Jersey, is a specialty pharmaceutical company which manufactures and sells pharmaceutical products, primarily aseptic injectable products into the hospital segment, and provides contract manufacturing of sterile products for innovator pharmaceutical companies. JHP markets 14 branded pharmaceutical products through its national sales and marketing infrastructure and contract manufactures pharmaceutical products for large proprietary pharmaceutical companies. JHP employs more than 350 staff in the USA in its manufacturing, sales & marketing and corporate areas. JHP is a private company wholly owned by JHP Holdings, LLC.

1. Ali SZ, Taguchi A, Rosenberg H. Malignant hyperthermia. Best Practice & Research Clinical Anaesthesiology. 2003;17:519-533. 2. AANA.org website. Available at http://www.aana.com/uploadedFiles/Resources/Practice_Documents/malignant_hyperthermia.pdf. Accessed July 10, 2009.
2. T. Krause, M. U. Gerbershagen, M. Fiege, R. Weißhorn, F. Wappler. Dantrolene – A review of its pharmacology, therapeutic use and new developments (p 364-373) Published Online: March 16 2004.
3. Rosenberg H, Fletcher JE. An update on the malignant hyperthermia syndrome. Ann Acad Med Singapore. 1994;23(suppl):84S-97S.