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Simulated IV Solutions from Wallcur: CDER Statement- FDA's Investigation into Patients being Injected

[Posted 1/14/2015]

AUDIENCE: Risk Manager, Health Professionals, Pharmacy

ISSUE: FDA and the Centers for Disease Control and Prevention (CDC) are continuing to investigate multiple instances of Wallcur's simulated intravenous (IV) saline products being administered to patients. These products are not sterile and should not be injected in humans or animals. So far, more than 40 patients have received infusions of the simulated saline products, and there have been many adverse events associated with these incidents including fever, chills, tremors and headache. Some patients were hospitalized, and there is one death associated with the use of these products; it is not known if this death is directly related to the use of the product.

BACKGROUND: Wallcur's simulated IV saline solution, Practi-0.9% sodium chloride solution, was shipped to medical clinics, surgical centers, and urgent care facilities in numerous states. While Sodium Chloride 0.9% Injection (IV normal saline) has been in tight supply, FDA has been working with manufacturers to increase supply. In addition, FDA is not objecting to the temporary distribution of additional IV normal saline from alternate sources Fresenius Kabi USA, Baxter Healthcare Corp., and B. Braun Medical Inc. Currently, there is supply available from several

manufacturers as posted on FDA's website.

RECOMMENDATION:

Healthcare Providers

Clinicians and office staff are encouraged to take steps to ensure IV solution simulation products are removed from office inventory to eliminate the possible injection of Wallcur simulated products into patients.

- Visually inspect all current IV saline solution bags. Ensure none of the bags are labeled "Wallcur," "Practi-products," "For clinical simulation," or "Not for use in human or animal patients."
- If you have products labeled with any of these words, or you suspect you may have received other products intended for training purposes, separate simulation products from existing inventory and contact your distributor for directions on how to return these products.
- If you have received Wallcur Practi-products by mistake, please contact the distributor, or Wallcur, LLC of San Diego for return instructions.
- Consider reviewing your office procedures and make sure there are procedures in place to visually inspect all future shipments of normal saline products to ensure they are for clinical use.

If you suspect that any Wallcur training IV products may have been administered to a patient, whether or not the incident has resulted in an adverse event:

- Evaluate all potentially exposed patients with new, or ongoing symptoms;
- Use appropriate treatment;
- Report suspected cases to the state health department; and
- Report any adverse events following use of these products to FDA's MedWatch program online or at 1-800-332-1088.

Patients

- Patients who believe they received an injection of Wallcur simulated IV solution should contact their health care provider.
- Patients who received simulated IV saline almost immediately upon injection experienced fever, chills, muscle aches, headaches, and some required hospitalization. In most reported cases, these signs and symptoms were immediately recognized and patients received appropriate medical attention.
- You may also file a report of the incident through FDA's MedWatch program, and assist the FDA with this ongoing investigation.
- If you know you will be receiving normal saline, ask your doctor or nurse to visually inspect the

bag, and ensure they are using normal saline for human use. Ensure the bag is not labeled or printed with any of the following: "Wallcur," "Practi-products," "For clinical simulation" or "Not for use in human or animal patients." If the saline bag contains any of these words, ask your health care provider NOT to administer the solution.

Wholesalers, Distributors, Suppliers

- Inspect your inventory and ensure you are not distributing simulated products as clinical use products.
- It is incumbent upon wholesalers, distributors, and suppliers to clearly and accurately label and distribute their products to prevent medical product mix-ups from occurring.
- If you suspect you may have distributed this product to clients by mistake, immediately attempt to recall the products and warn clients of the potential risks. You should also contact Wallcur, your distributor and file a report to FDA's MedWatch program.

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U.S. Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

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