Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

PharMEDium Services, LLC Issues Voluntary Nationwide Recall of all unexpired lots of Oxytocin Compounded with Either Lactated Ringers or Lactated Ringers and Dextrose Due to Sub-Potency

For Immediate Release

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Announcement

View Product Photos

PharMEDium Services, LLC (PharMEDium) is voluntarily recalling all unexpired lots of Oxytocin compounded with Lactated Ringers and all unexpired lots of Oxytocin compounded with Lactated Ringers and Dextrose products that were produced between July 6, 2017 and August 29, 2017 to the hospital/user level. The recall is being issued based on laboratory test results indicating a lower than expected potency on certain lots of Oxytocin compounded with Lactated Ringers and Oxytocin Compounded with Lactated Ringers and Dextrose which would lead to a lower dose being administered. While the lower than expected potency results affected only certain lots of Oxytocin compounded with Lactated Ringers and Oxytocin Compounded with Lactated Ringers and Dextrose, in an abundance of caution, PharMEDium is recalling all unexpired lots of Oxytocin compounded with Lactated Ringers and all unexpired lots of Oxytocin compounded with Lactated Ringers and Dextrose. To date, PharMEDium has received four reports of product complaints related to the products.

Per the oxytocin package insert, oxytocin is indicated for the initiation or improvement of uterine contractions, where this is desirable and considered suitable for reasons of fetal or maternal concern, in order to achieve vaginal delivery. It is indicated for (1) induction of labor in patients with a medical indication for the initiation of labor, such as Rh problems, maternal diabetes, preeclampsia at or near term, when delivery is in the best interests of mother and fetus or when membranes are prematurely ruptured and delivery is indicated; (2) stimulation or reinforcement of labor, as in selected cases of uterine inertia; (3) as adjunctive therapy in the management of incomplete or inevitable abortion. In the first trimester, curettage is generally considered primary therapy. In second trimester abortion, oxytocin infusion will often be successful in emptying the uterus. Other means of therapy, however, may be required in such cases or to control postpartum evacuation/ bleeding.

Although oxytocin is titrated based on clinical response, an extreme and unexpected reduction in dose than expected could lead to a delay in treatment, disruption of clinical care of the patient, and worsening of patient's conditions.

These products were packaged in ready to use intravenous bags. All unexpired lots of Oxytocin compounded with Lactated Ringers and all unexpired lots of Oxytocin compounded with Lactated Ringers and Dextrose are included in this recall. The product can be identified by referring to the sample labels provided. These products were distributed nationwide in the USA to hospitals/clinics.

PharMEDium Services is notifying customers of the voluntary recall by phone. Customers that have any of the affected medications that are being recalled should immediately quarantine the product, discontinue use and destroy per their hospital protocol. Customers with any of the affected medications can also reference PharMEDium Services website for more information on the specific lot numbers affected and contact information: **www.pharmedium.com (http://www.pharmedium.com)**.

Patients and healthcare providers with questions regarding this recall can contact PharMEDium Services Clinical Pharmacist at (847) 457-2220, Monday through Friday, between 8am and 5pm Central Standard Time or via e-mail at **shasan@pharmedium.com (mailto:shasan@pharmedium.com)**.

Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to the use of these products.

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

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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