The Small Print

*How to report side effects, find drug information and engage with CDER*

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Division of Drug Information (DDI)

- DDI is CDER's focal point for public inquiries regarding human drug products

- The mission of DDI is to optimize CDER's educational and communication efforts to our global community

- We support the FDA mission to promote and protect public health
Reporting Side Effects
FDA MedWatch Program

Reports about problems with medical products come IN to MedWatch

Safety information about medical products goes OUT to health professionals, patients, and consumers
Why Report?

Pre-Marketing Clinical Trials are limited to:

• Size of the patient population studied

• Narrow population – often not providing sufficient data on special groups

• Narrow indications studied

• Short duration
Benefits of Post-Marketing Monitoring

The ability to study the following:

• Low frequency reactions (not identified in clinical trials)

• High risk groups

• Long-term effects

• Drug-drug / food interactions

• Increased severity and / or reporting frequency of known reactions
Who Should Report?

Anyone can report a serious problem.

Walla Walla, WA – Pharmacist
Sacramento, CA – Nurse
Houston, TX – Dentist
Tallahassee, FL – Consumer
Portland, ME – Physician Assistant
One person can make a difference
What to Report

Any event that:

- Is fatal
- Is life-threatening
- Is permanently disabling
- Requires / prolongs hospitalization
- Causes a birth defect
- Requires intervention to prevent permanent impairment or damage
- Potential for harm / close calls (drugs or devices)
• How to Report:
  – Online (www.fda.gov/medwatch)
  – Download the form
    • Mail
    • Fax 1–800–332–0178

• For questions about the form: 1–800–332–1088
MedWatch Form 3500A

MANDATORY Form 3500A

- User Facilities (medical devices)
- Manufacturers
  - Drugs
  - Biologics
  - Human Cell and Tissue Products
  - OTC Products
  - Medical Devices
MedWatch Form 3500

1. Patient Identifier
2. Event or Problem
3. Reporter
4. Product
MedWatch Form 3500B

- Includes 4 primary components
  - Patient
  - Product
  - Event
  - Reporter

- User-friendly format for non-health care professionals
Reporting Online

MedWatch: The FDA Safety Information and Adverse Event Reporting Program

Your FDA gateway for clinically important safety information and reporting serious problems with human medical products.

Report a Problem

Safety Information

Stay Informed

What's New

- ABC Dophilus Powder by Solgar, Inc: Recall - Risk of Infection The product was found to contain Rhizopus oryzae, which may cause health problems to consumers, particularly premature infants/infants, children, and those with weakened immune systems. Posted 11/17/2014
- October 2014 Safety Labeling Changes includes 37 products with revisions to Prescribing Information. Posted 11/17/2014

Resources for You

- 2014 Safety Alerts for Human Medical Products
- Contact Information For Voluntary Adverse Event Reporting
- MedWatchLearn - Teaching students, health professionals, and consumers how to report problems to FDA
- Medical Product Safety Educational Resources
- Consumer-Friendly Reporting

Search the MedWatch Section

www.fda.gov/medwatch
MedWatch Online Voluntary Reporting Form

Welcome

What to Report to FDA MedWatch:

Use the MedWatch form to report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
- Medical devices (including in vitro diagnostic products)
- Combination products
- Special nutritional products (dietary supplements, infant formulas, and medical foods)
- Cosmetics
- Foods/beverages (including reports of serious allergic reactions)

Begin Report As a:
- Health Professional
- Consumer/Patient

Reporting Online Mobile-Friendly

www.fda.gov/medwatch/report
What Happens to Your MedWatch Report?

- Report is captured in a database.
- FDA safety evaluator reviews the report.
- FDA safety evaluator looks for similar reports.
- FDA review division may consult with manufacturer.
- FDA/manufacturer conducts further epidemiological studies or post-market clinical trials as needed.
How Can MedWatch Reports Result in Regulatory Action?

- Market Withdrawal
- REMS
- PMR/PMC Enhanced Pharmacovigilance
- Adverse Reactions
- Warnings And Precautions
- Boxed Warning
- Dear HCP Letter or DSC

REGULATORY ACTION
Find Drug Information
Recall – Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Wallcur Practi-0.9% Sodium Chloride-IV Bags 50 mL, 250 mL, 500 mL, and 1000 mL Wallcur Practi-0.9% Sodium Chloride-IV Bag with Distilled Water 100 mL

Contact:
Consumer:
619-702-4333

FOR IMMEDIATE RELEASE — January 7, 2015 — San Diego, CA — This letter is to notify you of a product recall involving Wallcur’s Pradi 0.9% sodium chloride IV bags supplied in 50 mL, 250 mL, 500 mL, and 1000 mL sizes and the Pradi 0.9% sodium chloride 100 mL IV solution bag with sterile distilled water.

As you know, all of Wallcur’s products are intended for training, simulation, and educational purposes only. Recently some of Wallcur’s training products were not used for their intended purpose. Specifically, despite the fact that the products are intended for “clinical simulation” only, we are aware of reports that these products have been used outside of their intended use and administered to patients. Because these products are not intended for human or animal administration, and are not sterile, administration of these products could result in adverse events.

We began shipping this product on May 22, 2014. Immediately examine your inventory, quarantine the products subject to recall, and return them to Wallcur. In addition, if you are a Wallcur distributor, or have further distributed or sold this product, please provide Wallcur with a list of your customers the products were distributed or sold to, and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter along with a copy of the enclosed product labels to make the products easily identifiable at the user level. Please also notify your customers that have purchased these products that the products are for demonstration, training, and educational purposes only and not for human or animal use.

Your assistance is appreciated and necessary to prevent use of these products in humans or animals. Please complete and return the enclosed response form as soon as possible. If you have any questions call Carla Sanderson at 619-702-4333.

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

In addition to the recall, as a precautionary measure, if you are a Wallcur distributor or reseller, we are requesting that you ensure your websites, catalogues, and other print materials advertising these products and any other Wallcur products prominently display the following language:

“THIS PRODUCT IS FOR TRAINING PURPOSES ONLY NOT FOR HUMAN OR ANIMAL INJECTION.”

Wallcur intends to add product enhancement labels containing similar language to the IV bags prior to future distribution.

FDA’s investigation into patients being injected with simulated IV fluids continues

[Updated: 04/16/15] FDA’s laboratory analysis of Wallcur’s simulated Pradi-0.9% sodium chloride IV is now complete. FDA sampled 11 of Wallcur’s simulated saline solution bags and identified large amounts of endotoxin and significant bacterial contamination in the samples.

These include bacteria (e.g., *Bacillus* spp., *Brevundimonas* spp., *Pseudomonas* spp., *Rhizobium* radiobacter, *Sphingomonas* koreensis, *Sphingomonas* trooperi, *Sphingobium* sp.). It is possible that additional bacteria are present in other bags that were not included in this analysis.

Laboratory testing confirmed that samples of Wallcur’s simulated Pradi-0.9% sodium chloride IV solution products that FDA tested did not contain:

- yeast or mold;
- significant levels of lead, arsenic, cadmium, cobalt, chromium, nickel, selenium, thallium, or vanadium;
- drugs or poisons;
- dihydrogen phosphate (phosphoric).

FDA is aware of more than 40 individuals who received infusions of the simulated Pradi-0.9% sodium chloride IV products. 23 of whom reported adverse events that ranged from flu-like symptoms to sepsis, a potentially life-threatening complication of an infection. Of those 23 individuals, 2 deaths and 11 hospitalizations were reported.

FDA is reiterating its previous recommendations that health care professionals and consumers to do the following:

- Visually inspect all current IV solution bags. Ensure none of the bags are labeled “Wallcur,” “Pradi-0.9% sodium chloride,” or “For clinical training purposes only.”
- Consider reviewing clinic procedures and make sure there are procedures in place to visually inspect all future shipments of IV products to ensure they are appropriate for patient use;
- Seek medical attention if you were given a simulated Pradi-0.9% sodium chloride product and you experience the symptoms described above;
- Report any suspected adverse events associated with accidental or intentional exposure to simulated products to FDA’s MedWatch program online or at 1-800-332-1088.
CDER Social Media

Over 152,000 subscribers

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- MedWatch Mailing List:

- Twitter: Follow us:
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- Drug Safety Communications:
Engage with CDER
2015 Write-in Campaigns

- Duchenne Muscular Dystrophy – Drisapersen, Eteplirsen
- Amyotrophic Lateral Sclerosis – Genervon’s GM604
- Clozapine REMS
- Country of Origin
- Vascepa
- Sayana Press
- Spinal Muscular Atrophy
- Move-On petition – Narcan
Talk to us

Division of Drug Information
Call: 855-543-3784
301-796-3400
Email: druginfo@fda.hhs.gov
Website: www.fda.gov/aboutDDI