

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

January 8, 2015

Florida Department of Health advises health care professionals not to inject patients with IV solutions from Wallcur, of San Diego

Dear Healthcare Partners:

Florida Department of Health is requesting that health care professionals report any administration of Wallcur IV training solutions to patients since January 1, 2014, whether the patient had adverse effects or not. Wallcur IV solution products have been distributed in Florida and have been linked to serious illness in at least one Florida resident.

FDA has become aware that some Wallcur training IV products have been distributed to health care facilities and administered to patients. There have been reports of serious adverse events associated with the use of certain of these products – i.e., Practi IV Solution Bags. An image of one of the Wallcur products can be seen at: <http://www.fda.gov/Drugs/DrugSafety/ucm428431.htm>.

Before administering IV solutions to patients, health care providers should carefully check the labels to ensure that the products are not training products, such as Practi IV Solution Bags marketed by Wallcur. Wallcur's training products, which may bear the words "for clinical simulation," are not to be administered to patients. Again, Wallcur IV solutions should not be administered to people or animals.

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

- 1) FDA's MedWatch Adverse Event Reporting program completing and submitting the report online at: <https://www.accessdata.fda.gov/scripts/medwatch/> **or** completing the form at: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf> and then submitting it via fax to 1-800-FDA-0178
- 2) Also report administration of Wallcur IV training products to the Florida Department of Health at 850-245-4401.

FDA will continue to investigate and monitor this issue, and will continue working with the Centers for Disease Control and Prevention and state health departments to keep health care professionals informed.

Sincerely,

Anna M. Likos, MD, MPH, Director
Division of Disease Control and Health Protection

Florida Department of Health

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