

April 4, 2010

FDA Safety Announcement: Soladek Vitamin Solution: Unapproved Product May Contain Dangerously High Levels of Vitamins A, D



AUDIENCE: Consumer

ISSUE: Tested samples of Soladek Vitamin Solution were found to contain elevated levels of vitamins A and D which were many times in excess of the recommended daily allowances of these vitamins. Intake of excessively high levels of these vitamins pose a risk to human health. Symptoms of vitamin A toxicity include anemia, anorexia, alopecia, joint pain, bone weakness, bulging eyes, liver abnormalities, and birth defects. Symptoms of vitamin D toxicity include weakness, fatigue, headache, nausea, vomiting, diarrhea, changes in mental status, increased blood pressure, abnormal heart rate or rhythm, kidney damage, and coma.

BACKGROUND: Soladek Vitamin Solution is marketed with claims that it treats “hypo and avitaminosis, rickets, growth, dentition, lactation, fractures, infection, convalescence, protection and regeneration of certain epithelium (bronchial, glandular, ocular, cutaneous) corticotherapy, aging, and pregnancy.

The FDA has received seven reports of serious health problems occurring in consumers using this product. The problems include decreased renal function, elevated levels of calcium in the blood, fatigue, heart arrhythmia, vomiting, and diarrhea. The product is sold in a box labeled in Spanish and containing a vial of the solution.

RECOMMENDATION: Consumers who are in possession of Soladek should stop using the product immediately. Any consumer who have been using Soladek and are experiencing any of the above symptoms should see a doctor immediately.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) 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

Read the MedWatch safety alert, including a link to the Press Release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm248738.htm>

www.kcercoalition.com/alerts.htm