Soladek Vitamin Solution: Unapproved Product May Contain Dangerously High Levels of Vitamins A and D

U.S. Food & Drug Administration

AUDIENCE: Consumer

ISSUE: Tested samples of Soladek contained levels of vitamin A and vitamin D that were many times the recommended daily allowances for these vitamins. Intake of excessively high levels of these vitamins poses 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 is marketed with claims that the product 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 product is sold in a box labeled in Spanish and containing a vial of the solution.

The FDA received seven reports of serious health problems occurring in consumers using the product. The problems include decreased renal function, elevated levels of calcium in the blood, fatigue, heart arrhythmia, vomiting, and diarrhea.

RECOMMENDATION: Consumers who are in possession of Soladek should stop using the product immediately. Any consumers 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 these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] 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

[03/28/2011 - Press Release [3] - Indo Pharma, S.A.]

SOURCE [4]

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[1] http://www.fda.gov/MedWatch/report.htm
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