Reumofan Plus: Recall - Undeclared Drug Ingredient

U.S. Food & Drug Administration

AUDIENCE: Consumer, Health Professional, Emergency Medicine

ISSUE: FDA is warning consumers that Reumofan Plus, marketed as a natural dietary supplement for pain relief and other serious conditions, contains several active pharmaceutical ingredients not listed on the label that could be harmful. An FDA laboratory analysis of Reumofan Plus found that it contains Diclofenac Sodium, a prescription non-steroidal anti-inflammatory drug (NSAID) that may cause increased risk of cardiovascular events such as heart attack and stroke, as well as serious gastrointestinal (GI) adverse events including bleeding, ulceration, and fatal perforation (causing a hole) of the stomach and intestines, and Methocarbamol, a prescription muscle relaxant that can cause sedation, dizziness, low blood pressure, and impair mental or physical abilities to perform tasks such as driving a motor vehicle or operating machinery.

The Mexican Ministry of Health discovered that at least one lot of the product contains the corticosteroid dexamethasone, a drug that acts as an anti-inflammatory and immune system suppressant.

FDA has received multiple reports of adverse events associated with the use of Reumofan Plus, including liver injury, sudden worsening of glucose control, weight gain, swelling, leg cramps, and adrenal suppression.

BACKGROUND: Reumofan Plus is marketed as a natural dietary supplement for pain relief. Reumofan Plus is labeled in Spanish and promoted for treating arthritis, muscle pain, osteoporosis, bone cancer, and other conditions. The product is manufactured in Mexico by Riger Naturals and sold in some retail outlets, at flea markets, and on various internet sites. FDA has worked closely with the Mexican government on this matter. The Mexican Ministry of Health has issued a health warning to the public and ordered Riger Naturals to recall the product.

RECOMMENDATION: Consumers who are currently taking or who recently stopped taking Reumofan Plus are urged to consult a healthcare professional immediately. Health care professionals are urged to ask their patients about use of Reumofan Plus and other products marketed as dietary supplements when patients present with unexplained symptoms that suggest NSAID toxicity, depression, or the use or abrupt discontinuation of corticosteroids. Additionally, health care professionals should evaluate patients who have used Reumofan Plus for drug and disease interactions involving diclofenac, methocarbamol, and corticosteroids, and consider whether a corticosteroid taper regimen may be appropriate in those who have used

Reumofan Plus.

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

[06/01/2012 - News Release [3] - FDA]

SOURCE [4]

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