Reumofan Plus: Recall - Undeclared Drug Ingredient

[UPDATED 03/14/2014]

Pain Free By Nature is recalling "Reumofan Plus" Tablets purchased through their website at www.painfreebynature.com, after FDA discovered that the product was distributed in packaging that did not reveal the presence of the active pharmaceutical ingredients methocarbamol and diclofenac, making it an unapproved drug. Use of this product could result in serious and life-threatening injuries. Distribution has been completely terminated by the company.

Reumofan Plus is used as a treatment for muscle pain, arthritis, osteoporosis, bone cancer and other conditions. This product comes in thirty (30) tablet containers and is packaged in a green and gold box [photo link below]. Consumers who are taking these products or who have recently stopped taking Reumofan Plus should immediately consult a health care professional.

[UPDATED 02/19/2013]

Reumofan Plus USA, LLC and Reumofan USA, LLC is recalling "Reumofan Plus" Tablets, Lot# 99515, exp. 09/16, because they contain undeclared active pharmaceutical ingredients: methocarbamol, dexamethasone, and diclofenac. The recall was initiated after it was discovered that the product was distributed in packaging that did not reveal the presence of the active pharmaceutical ingredients, making it an unapproved drug. One illness has been reported to date in connection with this problem.

[UPDATED 08/28/2012]

Samantha Lynn Inc. is voluntarily recalling 500 lots of Reumofan Plus Tablets to the consumer level due to findings of undeclared drug ingredients. The FDA sample analysis has found the product to contain methocarbamol and diclofenac. The affected Reumofan Plus lots may include the following lot number(s): 99515 ex096 and expires: 2016. The product is marketed in a green bottle containing 30 lavender round tablets and is distributed nationwide via the internet.

Consumers that purchased Reumofan Plus from Samantha Lynn Inc. between Feb 2012 and June 2012 will receive an email notifying them of their options. Consumers that have Reumofan Plus should be aware that the product may pose a health risk and are advised to consult their family doctor/stop using/return to place of purchase or discard.
[UPDATED 08/21/2012]

FDA is issuing an updated alert that Reumofan Plus and Reumofan Plus Premium contain undeclared active ingredients found in prescription drugs that should be used only under the supervision of a health care professional.

Since June 1, 2012, when FDA first warned the public about the dangers of these supplements, the agency has received reports of fatalities, stroke, severe bleeding in the gastrointestinal tract, dizziness, insomnia, high blood sugar levels and problems with liver and kidney functions,as well as corticosteroid withdrawal syndrome

Because of the possible risks, consumers should not buy or start using these products.

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 (/web/20160818024151/http://www.fda.gov/MedWatch/report.htm)**
- **Download form (/web/20160818024151/http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm)** 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

[03/14/2014 - **Firm Press Release (/web/20160818024151/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/ucm389049.htm)** - Pain Free By Nature]
[03/14/2014 - **Comunicado de Prensa de la Compañía (/web/20160818024151/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/ucm389293.htm)** - Pain Free By Nature]
[03/14/2014 - **Product Labels (/web/20160818024151/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/ucm389050.htm)** - Pain Free By Nature/FDA]

[02/15/2013 - **Firm Press Release (/web/20160818024151/http://www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/ucm340161.htm)** - Reumofan P

[08/24/2012 - **Firm Press Release (ssLINK/UCM317114)** - Samantha Lynn]

[08/21/2012 - **News Release (/web/20160818024151/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm316469.htm)** - FDA]
[08/21/2012 - **Consumer Update (/web/20160818024151/http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm316315.htm)** - FDA]
[06/01/2012 - **News Release (/web/20160818024151/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm306348.htm)** - FDA]

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