FDA NEWS RELEASE

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En Español (/web/20170111234836/https://www.fda.gov/NewsEvents/Newsroom/ComunicadosdePrensa/ucm316525.htm)

FDA issues new safety alert on Reumofan Plus and Reumofan Plus Premium

The U.S. Food and Drug Administration today issued a new warning to consumers about the potential health risks of two products marketed as natural dietary supplements for treating arthritis, muscle pain, osteoporosis, bone cancer, and other conditions. The products, Reumofan Plus and Reumofan Plus Premium, contain several potentially harmful active pharmaceutical ingredients that are not listed on the product labels.

The FDA has received dozens of additional adverse event reports, including death and stroke, associated with the use of Reumofan Plus since the agency issued its **first warning (/web/20170111234836/https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm306348.htm)** about the product on June 1, 2012. Other reports include liver injury, severe bleeding, sudden worsening of glucose (sugar) control, weight gain, swelling, leg cramps and withdrawal syndrome, and adrenal suppression.

Consumers who are taking these products or who have recently stopped taking Reumofan Plus or Reumofan Plus Premium should immediately consult a health care professional. Consumers should not buy or start using these products.

Ongoing FDA laboratory analyses of Reumofan Plus found that it contains the prescription drug ingredients:

- dexamethasone – a corticosteroid, commonly used to treat inflammatory conditions, that can impair the body's ability to fight infections and cause high blood sugar levels, bone and muscle injuries, and psychiatric problems. Dexamethasone can also cause adrenal suppression when taken for a prolonged period of time or at high doses. Sudden discontinuation of corticosteroids after long-term use or use at high doses can result in a withdrawal syndrome that includes fatigue, nausea, low blood pressure, low blood sugar levels, fever, dizziness, and muscle and joint pain.

- diclofenac sodium – a 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 of the stomach and intestines.

- methocarbamol – a 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.

A separate FDA lab analysis of Reumofan Plus Premium found that it contains two of the ingredients listed above, diclofenac sodium and methocarbamol.

Reumofan Plus and Reumofan Plus Premium are labeled in Spanish. However, versions of these products may also exist with English labeling.

The products are manufactured in Mexico by Riger Naturals and sold in the U.S. in some retail outlets, at flea markets, and on various popular Internet sites.

The hidden drug ingredients in Reumofan Plus and Reumofan Plus Premium may interact with other medications and result in serious adverse events. Health care professionals are urged to ask their patients about use of Reumofan Plus, Reumofan Plus Premium, and other similar products marketed as dietary supplements when patients present with unexplained symptoms that suggest NSAID toxicity, psychiatric changes, or the use or abrupt discontinuation of corticosteroids.

Additionally, health care professionals should evaluate patients who have used Reumofan Plus and/or Reumofan Plus Premium for drug and disease interactions involving diclofenac, methocarbamol, and corticosteroids, and consider whether a corticosteroid taper regimen may be appropriate.

Health care professionals and consumers are encouraged to report any adverse events related to Reumofan Plus and Reumofan Plus Premium to FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- online at **www.fda.gov/Medwatch/report.htm (https://web.archive.org/web/20170111234836/http://www.fda.gov/Medwatch/report.htm)**;

- by phone at 800-FDA-1088 (800-332-1088); or,
- by returning FDA form 3500, available on the MedWatch “Download Forms” page by mail to the address on the pre-addressed form or by fax at 800-FDA-0178.

For more information:

- **Reumofan Products Pose Risk to Consumers (/web/20170111234836/https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm316315.htm)**
- **Consumer Q&As (/web/20170111234836/https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm316478.htm)**
- **Reumofan Plus Recall (/web/20170111234836/https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm306360.htm)**
- **Reumofan Plus Recall En Español (/web/20170111234836/https://www.fda.gov/Safety/Recalls/ArchiveRecalls/2013/ucm340843.htm)**

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