FDA Orders Halt to Marketing of Unapproved Single-Ingredient Oral Colchicine

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SILVER SPRING, Md., Sept. 30 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration today took action against companies that manufacture, distribute, and/or market unapproved single-ingredient oral colchicine, a medication commonly used for the daily prevention of gout, to treat acute gout flare-ups, and for the treatment of Familial Mediterranean Fever (FMF).

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The companies are expected to stop manufacturing single-ingredient oral colchicine within 45 days and must stop shipping this unapproved product in interstate commerce within 90 days. A small amount of unapproved colchicine is expected to be available after these dates until supplies are exhausted.

Many single ingredient oral colchicine products have been used by the medical community for decades. These and a variety of other medications have not received the mandatory modern-day FDA-approval required of all prescription drugs.

Colcrys is the only FDA-approved single-ingredient oral colchicine product available on the U.S. market. Approved by the FDA in 2009, Colcrys' prescribing information contains important safety data and recommendations on drug interactions and dosing not available with unapproved product [3]s.

The manufacturer of Colcrys, Mutual Pharmaceutical/URL Pharma, has established a Patient Assistance Program (PAP) and a Co-Pay Assistance Program (CAP) to ensure that all patients will be able to continue affordable access to colchicine. The company also has informed FDA that it will maintain the programs at a minimum until there is FDA-
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