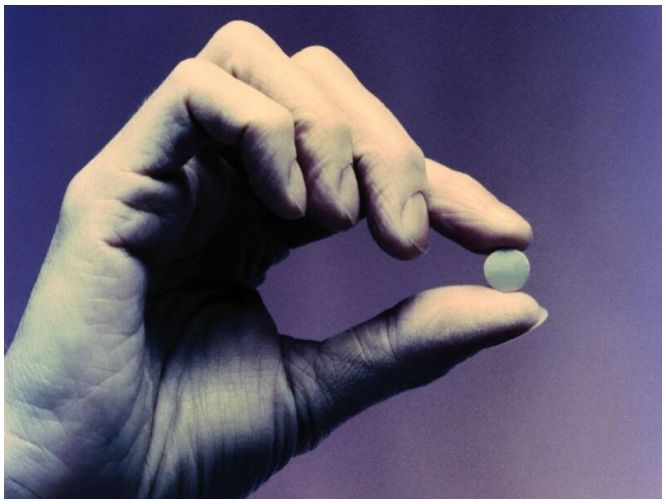
FDA: Gout drug uloric increases risk of death

25 February 2019



(HealthDay)—The gout medicine Uloric (febuxostat) carries a higher risk of death than allopurinol, according to the U.S. Food and Drug Administration.

The agency said its in-depth review of results from a safety clinical trial found that Uloric was associated with an increased risk of heart-related death and death from all causes.

Due to these findings, the FDA said it is updating Uloric prescribing information to require a Boxed Warning—the most prominent warning—and a new patient Medication Guide. The agency is also limiting the use of Uloric to certain patients who do not get effective results or suffer severe side effects when taking allopurinol. Health care professionals should counsel patients about the cardiovascular risk with Uloric and advise them to seek medical attention immediately if they experience symptoms such as chest pain, shortness of breath, rapid or irregular heartbeat, numbness or weakness on one side of the body, dizziness, trouble talking, and sudden severe headache.

The FDA approved Uloric in 2009 to treat adults with gout, a chronic disease that affects about 8.3 million U.S. adults. Only a few medicines are available to treat gout.

More information: More Information