

March 1, 2019

## COM-2019-010

## **Uloric: Boxed Warning Communication Update**

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on February 21, 2019 the US Food and Drug Administration (FDA) published a communication notifying an increased risk of death with Uloric (febuxostat) compared to allopurinol, based on the results from a safety clinical trial.

Therefore, the FDA is updating the Uloric prescribing information adding a Boxed Warning, developing a new patient Medication Guide, and limiting the use of this medication to specific patients according to their side effects profile. This published statement included some important suggestions for health care professionals and patients regarding the use of Uloric.

Health Care Professionals	Patients
<ul> <li>Follow the recommendations in the Uloric prescribing information for the specific condition.</li> <li>Reserve this medication to patients who have failed or do not tolerate allopurinol.</li> <li>Educate patients regarding the cardiovascular risk associated with Uloric.</li> </ul>	<ul> <li>Do not stop Uloric without talking to the health care professional.</li> <li>Tell the doctor if you have a history of heart problems or stroke.</li> <li>Seek medical attention if experience the following symptoms while taking Uloric:         <ul> <li>Chest pain</li> <li>Shortness of breath</li> <li>Rapid or irregular heartbeat</li> <li>Numbness or weakness on one side of your body</li> <li>Dizziness</li> <li>Difficulty to talk</li> <li>Sudden severe headache</li> </ul> </li> </ul>

## For additional information visit:

https://www.fda.gov/downloads/Drugs/DrugSafety/UCM631586.pdf

Department of Clinical Pharmacy

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