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FDA adds Boxed Warning for increased risk of death with gout medicine Uloric (febuxostat)

On February 21, 2019, The U.S. Food and Drug Administration (FDA) has concluded there is an increased risk of death with Uloric (febuxostat) compared to another gout medicine, allopurinol. This conclusion is based on the FDA’s in-depth review of results from a safety clinical trial that found an increased risk of heart-related death and death from all causes with Uloric.

As a result, the FDA is updating the Uloric prescribing information to require a Boxed Warning, our most prominent warning, and a new patient Medication Guide. They are also limiting the approved use of Uloric to certain patients who are not treated effectively or experience severe side effects with allopurinol.

Uloric was FDA-approved in 2009 to treat a type of arthritis called gout in adults. Gout happens when a naturally occurring substance in the body called uric acid builds up and causes sudden attacks of redness, swelling, and pain in one or more joints. Uloric works by lowering uric acid levels in the blood. Gout is a chronic disease that affects approximately 8.3 million adults in the U.S. The number of medicines to treat gout is limited and there is an unmet need for treatments for this disease.

Healthcare professionals should reserve Uloric for use only in patients who have failed or do not tolerate allopurinol. Counsel patients about the cardiovascular risk with Uloric and advise them to seek medical attention immediately if they experience the symptoms listed above.

When the FDA approved Uloric in 2009, they included a Warning and Precaution regarding possible cardiovascular events in patients treated with Uloric in the current prescribing information and required the drug manufacturer, Takeda Pharmaceuticals, to conduct a large postmarket safety clinical trial. The trial was conducted in more than 6,000 patients with gout treated with either Uloric or allopurinol. The primary outcome was a combination of heart-related death, non-deadly heart attack, non-deadly stroke, and a condition of inadequate blood supply to the heart requiring intervention, called unstable angina.

The results showed that overall, Uloric did not increase the risk of these combined events compared to allopurinol (See Data Summary). However, when the outcomes were evaluated separately, Uloric showed an increased risk of heart-related deaths and death from all causes. In patients treated with Uloric, 15 deaths from heart-related causes were observed for every 1,000 patients treated for a year compared to 11 deaths from heart-related causes per 1,000 patients treated with allopurinol for a year. In addition, there were 26 deaths from any cause per 1,000 patients treated for a year with Uloric compared to 22 deaths per 1,000 patients treated for a year with allopurinol. This safety trial was also discussed at a public Advisory Committee meeting of outside experts on January 11, 2019.

To help FDA track safety issues with medicines, the FDA urges patients and healthcare professionals to report side effects involving Uloric or other medicines to the FDA MedWatch program.

For more Info
855-543-DRUG (3784) and press 4
druginfo@fda.hhs.gov

If you have questions, contact AlohaCare Provider Relations at 973-1650 or toll-free at 1-800-434-1002.