



FDA to evaluate increased risk of heart-related death and death from all causes with the gout medicine febuxostat (Uloric)

Safety Announcement

[11-15-2017] The U.S. Food and Drug Administration (FDA) is alerting the public that preliminary results from a safety clinical trial show an increased risk of heart-related death with febuxostat (Uloric) compared to another gout medicine called allopurinol. We required the Uloric drug manufacturer, Takeda Pharmaceuticals, to conduct this safety study when we approved the medicine in 2009. Once we receive the final results from the manufacturer, we will conduct a comprehensive review and will update the public with any new information.

Febuxostat is FDA-approved 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. Febuxostat works by lowering uric acid levels in the blood.

Health care professionals should consider this safety information when deciding whether to prescribe or continue patients on febuxostat. **Patients** should talk to your health care professionals if you have any questions or concerns. Do not stop taking your medicine without first consulting with your health care professional.

The febuxostat drug labels already carry a *Warning and Precaution* about cardiovascular events because the clinical trials conducted before approval showed a higher rate of heart-related problems in patients treated with febuxostat compared to allopurinol. These problems included heart attacks, strokes, and heart-related deaths. As a result, we required an additional safety clinical trial after the drug was approved and on the market to better understand these differences, and that trial was finished recently.

The safety trial was conducted in over 6,000 patients with gout treated with either febuxostat 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 urgent surgery. The preliminary results show that overall, febuxostat did not increase the risk of these combined events compared to allopurinol. However, when the outcomes were evaluated separately, febuxostat showed an increased risk of heart-related deaths and death from all causes.

We are continuing to evaluate this safety issue and will update the public when we have more information. We urge health care professionals and patients to report side effects involving febuxostat or other medicines to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.

Related Information

[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)

[Think It Through: Managing the Benefits and Risks of Medicines](#)