Uloric® (febuxostat) – Safety update

- On November 15, 2017, the FDA announced that preliminary results from a post-marketing safety study showed an increased risk of heart-related death and death from all causes with Uloric (febuxostat) compared to allopurinol.

- Uloric is indicated for the chronic management of hyperuricemia in patients with gout.

- Allopurinol is indicated for the following:

    - Management of patients with signs and symptoms of primary or secondary gout (acute attacks, tophi, joint destruction, uric acid lithiasis, and/or nephropathy).
    - Management of patients with leukemia, lymphoma and malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels.
    - Management of patients with recurrent calcium oxalate calculi whose daily uric acid excretion exceeds 800 mg/day in male patients and 750 mg/day in female patients.

- Healthcare providers should consider this safety information when deciding whether to prescribe or continue patients on Uloric.

- Patients should talk to their healthcare providers if they have any questions or concerns. Patients should not stop taking their medicine without first consulting with their healthcare provider.

- The Uloric drug label already carries a *Warning and Precaution* about cardiovascular events. Pre-approval studies showed a higher rate of heart attacks, strokes, and heart-related deaths with Uloric vs. allopurinol. As a result, the FDA required an additional post-marketing safety study to better understand these differences.

- The post-marketing safety study was conducted in over 6,000 patients with gout treated with Uloric or allopurinol. The primary outcome was a combination of heart-related death, non-fatal heart attack, non-fatal stroke, and a condition of inadequate blood supply to the heart requiring urgent surgery.

    - The preliminary results show that overall, Uloric did not increase the risk of these combined events compared to allopurinol.
    - However, when the outcomes were evaluated separately, Uloric showed an increased risk of heart-related deaths and death from all causes.

- The FDA is conducting a comprehensive review of this safety information and will update the public when more information is available.