Zurampic Approved for Gout

AstraZeneca received approval from the U.S. Food and Drug Administration (FDA) on Dec. 22, 2015 for Zurampic® (lesinurad), a selective uric acid resorption inhibitor for treating hyperuricemia (high uric acid levels in the blood) associated with gout. Zurampic should be used in combination with a xanthine oxidase inhibitor (XOI), such as allopurinol or febuxistat, which lowers the production of uric acid. The recommended dose for Zurampic is one 200mg tablet daily along with an XOI. A boxed warning cautions that a small number of clinical-trial patients experienced acute kidney failure when taking Zurampic, most often when it was used by itself without an XOI. To limit possible kidney damage, no more than 200mg of Zurampic should be taken per day. Full prescribing information is at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207988lbl.pdf

At a Glance

- **Brand (Generic) Name:** Zurampic® (lesinurad)
- **Manufacturer:** AstraZeneca
- **Date Approved:** Dec. 22, 2015
- **Indication:** for the treatment of hyperuricemia associated with gout in combination with a xanthine oxidase inhibitor (XOI) for patients who have not achieved target serum uric acid levels with an XOI alone
- **Dosage Forms Available:** 200mg oral tablets
- **Launch Date:** First quarter 2016
- **Estimated Annual Cost:** AstraZeneca has not yet announced pricing for Zurampic.
- **Gout** is a type of inflammatory arthritis that results when urate crystals collect in joints – usually in the feet and hands, often in the big toe. It causes sudden and severe inflammation pain, redness and swelling at the affected joints. Although acute symptoms typically lessen over a few hours or days, tenderness may last for weeks. If not treated, gout can damage joints enough to cause chronic pain and disability.
- According to the U.S. Centers for Disease Control and Prevention (CDC), about 3.8% of American adults had some degree of gout in 2010, up from about 2.7% in 1994. Significantly more men are affected than women; African Americans have a higher risk than other U.S. ethnic groups; and risk climbs with increasing age and weight. As the population ages and obesity is more prevalent, cases of gout are expected to increase, as well.
- Drugs previously approved for treating gout prevent the formation of uric acid, increase its elimination or break it down enzymatically.
- By blocking urate transporter 1 (URAT1), Zurampic reduces the reabsorption of uric acid in the kidneys and forces more of it to be eliminated in urine.
- Labeling for Zurampic carries a boxed warning about the possibility of acute kidney failure when taking it.
• Additionally, AstraZeneca will conduct further studies to evaluate both kidney and cardiovascular risks with its use.
• Even with treatment, uric acid levels can remain high for many patients. Zurampic will offer another treatment option in patients who cannot achieve serum uric acid goals with a XOI alone.