Zurampic

(lesinurad)

New Product Slideshow
Introduction

- **Brand name:** Zurampic
- **Generic name:** Lesinurad
- **Pharmacological class:** URAT1 inhibitor
- **Strength and Formulation:** 200mg; tablets
- **Manufacturer:** Ironwood
- **How supplied:** Bottles—5, 30, 90
- **Legal Classification:** Rx
Indications

- In combination with a xanthine oxidase inhibitor (including allopurinol or febuxostat), to treat hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.
Limitations of Use

- **Not** for treatment of asymptomatic hyperuricemia
- **Not** for use as monotherapy
Dosage & Administration

- Take in the AM with food and water
- 200mg once daily with a xanthine oxidase inhibitor
- Max 200mg daily
- Patients on daily allopurinol dose <300mg (or <200mg with eCLCr <60mL/min): not recommended
Considerations for Special Populations

- **Pregnancy**: No human data to inform a drug-associated risk

- **Nursing mothers**: Consider benefits and potential adverse effects

- **Pediatric**: <18yrs: not established

- **Geriatric**: No overall differences in safety or efficacy observed

- **Hepatic impairment**: Severe: not recommended

- **Renal impairment**: See Warnings/Precautions
Contraindications

- Severe renal impairment (eCLCr <30mL/min), ESRD, kidney transplant recipients, or dialysis patients

- Tumor lysis syndrome or Lesch-Nyhan syndrome
Warnings/Precautions

- Risk of acute renal failure when used without a xanthine oxidase inhibitor
- Assess renal function prior to initiation and periodically thereafter
- **Renal impairment** (eCLCr < 45mL/min): do not initiate
- If eCLCr < 60mL/min or with serum creatinine (SCr) elevations 1.5–2X pre-treatment value: monitor more frequently; if SCr > 2X pre-treatment value: interrupt treatment
Discontinue therapy if eCLCr is persistently <45mL/min

Maintain adequate hydration (2 liters of liquid per day)

Give gout flare prophylaxis

Females should use additional non-hormonal methods of contraception
Interactions

- Caution with concomitant moderate CYP2C9 inhibitors (eg, fluconazole, amiodarone) and in CYP2C9 poor metabolizers

- Antagonized by moderate CYP2C9 inducers (eg, rifampin, carbamazepine), aspirin >325mg/day (in combination with allopurinol)
Interactions

- Antagonizes CYP3A substrates (eg, sildenafil, amlodipine)
- May affect sensitive CYP3A substrates (eg, HMG-CoA reductase inhibitors); monitor
- Concomitant epoxide hydrolase inhibitors (eg, valproic acid): not recommended
- May reduce efficacy of hormonal contraceptives
Adverse Reactions

- Headache
- Influenza
- Blood creatinine increase
- GERD
- Gout flares
- Renal events
- Cardiovascular events
Lesinurad reduces serum uric acid levels by inhibiting the function of transporter proteins involved in uric acid reabsorption in the kidney.
The efficacy of Zurampic 200mg and Zurampic 400mg once daily was studied in 3 multicenter, randomized, double-blind, placebo-controlled studies in adults with hyperuricemia and gout in combination with allopurinol or febuxostat; prophylaxis with colchicine or NSAIDs for the first 5 months of Zurampic therapy were given
In **Study 1** (n=603) and **Study 2** (n=610), Zurampic 200mg with allopurinol was superior to allopurinol alone in lowering serum uric acid to <6mg/dL at Month 6.

In **Study 3**, gout patients with measurable tophi were randomized to Zurampic 200mg, Zurampic 400mg, or placebo in combination with febuxostat.
There was no statistical difference in the proportion of patients treated with Zurampic 200mg in combination with febuxostat achieving serum uric acid <5mg/dL by Month 6 compared with febuxostat alone.

The rates of gout flare requiring treatment from Month 6 to 12 were not statistically different between Zurampic with allopurinol or febuxostat compared with allopurinol or febuxostat alone.
In Study 3, the proportion of patients who had complete resolution of ≥1 tophus did not statistically differ between Zurampic with febuxostat compared with febuxostat alone.

For more clinical trial data, see full labeling.
For more information view the product monograph available at:

http://www.empr.com/zurampic/drug/34561/