



## Preferred Drug List

### NEW DRUG REVIEW

**Proprietary Name:** Uloric®

**Common Name:** Febuxostat

**PDL Category:** Gout

| <u>Comparable Products</u> | <u>Preferred Drug List Status</u> |
|----------------------------|-----------------------------------|
| Allopurinol                | Preferred                         |

#### Summary

**Indications and Usage:** Chronic management of hyperuricemia in patients with gout.<sup>1</sup>

**Mechanism of Action:** Blockade of the enzyme xanthine oxidase which prevents uric acid production, thereby lowering elevated levels of serum uric acid.<sup>1</sup>

**Dosage Forms:** Tablets: 40mg and 80mg

**Recommended Dosage:** The recommended starting dose is 40 mg once daily. For patients who do not achieve a serum uric acid (sUA) less than 6 mg per dL after 2 weeks with the 40 mg dose, 80 mg is recommended.<sup>1</sup>

**Common Adverse Drug Reactions:** Liver function abnormalities, nausea, arthralgia, and rash.<sup>1</sup>

**Contraindications:** Patients being treated with azathioprine, mercaptopurine, or theophylline.<sup>1</sup>

**Manufacturer:** Takeda Pharmaceuticals America, Inc.

**Analysis:** Uloric® is a selective xanthine oxidase inhibitor indicated for the long-term treatment of chronic hyperuricemia in patients with gout. FDA approval was based on clinical trials comparing varying doses of Uloric® to allopurinol over 6-12 months. The 80-mg dose of Uloric® was more effective than allopurinol 300/200mg and the 40-mg dose was as effective as allopurinol 300/200mg in lowering serum uric acid. Dose adjustment of Uloric® is not necessary in patients with mild to moderate renal failure. During trials, Uloric® was associated with a higher rate of cardiovascular thromboembolic events as compared to placebo and allopurinol, although the number of events was small. Preferred alternatives appear on the Preferred Drug List, which have similar clinical efficacy and are more cost effective. Therefore, it is recommended that Uloric® be added to the Preferred Drug List as a non-preferred drug.

**IME Recommendation:**

|   |   |
|---|---|
| <input type="checkbox"/> Preferred Drug                 | <input type="checkbox"/> Recommended Drug     |
| <input checked="" type="checkbox"/> Non-Preferred Drug  | <input type="checkbox"/> Non-Recommended Drug |
| <input type="checkbox"/> Preferred Drug with Conditions |   |

1. Uloric® [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; 2009.