

## ULORIC Now Approved

Introducing a new treatment for the chronic management of hyperuricemia in patients with gout.

### ULORIC efficacy

Proportion of patients with serum uric acid levels of <6.0 mg/dL at final visit <sup>1</sup>						
Study*	ULORIC 40 mg daily	ULORIC 80 mg daily	Allopurinol	Placebo	Difference in Proportion (95% CI)	
					ULORIC 40 mg vs Allopurinol	ULORIC 80 mg vs Allopurinol
Study 1 (6 months) (N=2268)	45%	67%	42%		3% (-2%, 8%)	25% (20%, 30%)
Study 2 (6 months) (N=643)		72%	39%	1%		33% (26%, 42%)
Study 3 (12 months) (N=491)		74%	36%			38% (30%, 46%)

\* Randomization was balanced between treatment groups, except in Study 2, in which twice as many patients were randomized to each of the active treatment groups compared with placebo.

### How to order ULORIC

NDC#	Strength	Form	Quantity
64764-918-30	40 mg	Tablet	30 tablets
64764-677-30	80 mg	Tablet	30 tablets

For questions or to place orders, contact your wholesaler.

### ULORIC offers simple, once-daily dosing<sup>1</sup>

- ULORIC 40 mg or 80 mg QD<sup>1</sup>



40- and 80-mg tablets (not actual size)



### Product description

- ULORIC 40-mg tablets are light green to green in color, circular, debossed with "TAP" on one side and "40" on the other side
- ULORIC 80-mg tablets are light green to green in color, teardrop-shaped, debossed with "TAP" on one side and "80" on the other side

### Storage

- Protect from light. Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F). See USP Controlled Room Temperature.



## ULORIC has been extensively studied

- › In more than 4000 patients<sup>2</sup>
- › In some for up to five years<sup>2</sup>

### Identifying the right patient for ULORIC

ULORIC may reduce elevated serum uric acid in chronic gout patients who present with:

- high serum uric acid levels
- flares
- mild to moderate renal impairment

As with any anti-hyperuricemic agent, including ULORIC, gout flares are frequently observed during the initiation of therapy. Gout flares may occur due to changing serum uric acid levels resulting in mobilization of urate from tissue deposits. Flare prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended upon initiation of ULORIC and may be beneficial for up to six months. If a gout flare occurs during ULORIC treatment, ULORIC need not be discontinued.<sup>1</sup>

### Indication

ULORIC is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout. ULORIC is not recommended for the treatment of asymptomatic hyperuricemia.

### Important Safety Information

- ULORIC is contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline.
- An increase in gout flares is frequently observed during initiation of anti-hyperuricemic agents, including ULORIC. If a gout flare occurs during treatment, ULORIC need not be discontinued. Prophylactic therapy (i.e. - NSAIDs or colchicine) upon initiation of treatment may be beneficial for up to six months.
- A higher rate of cardiovascular thromboembolic events was observed in patients treated with ULORIC than allopurinol in clinical trials. A causal relationship with ULORIC has not been established. Monitor for signs and symptoms of MI and stroke.
- Transaminase elevations have been observed in ULORIC-treated patients. No dose-effect relationship for these transaminase elevations was noted. Monitor liver function tests periodically.
- Adverse reactions occurring in at least 1% of ULORIC-treated patients, and, at least 0.5% greater than placebo, are liver function abnormalities, nausea, arthralgia, and rash.

Please click here for complete Prescribing Information.

#### References:

1. ULORIC (febuxostat) full prescribing information, February 2009.
2. Data on file, Takeda Pharmaceuticals North America, Inc.



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NEW  
**Uloric**  
(febuxostat) tablets