ZOLINZA: An HDAC Inhibitor With Proven Efficacy in Advanced CTCL



Substantial Clinical Efficacy With a Durable Response

- 30% (22/74) of heavily pretreated patients with advanced CTCL achieved an objective response in the pivotal trial.
 - 6/74 patients taking ZOLINZA continued on therapy for ≥2 years.¹
- Median response duration was estimated to exceed 6 months in responders.

Most Adverse Events in Clinical Trials Were Grade 1 or 2

Convenient Oral Once-Daily Dosage

ZOLINZA is an HDAC inhibitor indicated for treatment of cutaneous manifestations in patients with CTCL who have progressive, persistent, or recurrent disease on or following 2 systemic therapies.

Selected Important Safety Information

- Pulmonary embolism and deep vein thrombosis have been reported. Monitor patients for pertinent signs and symptoms, particularly in patients with a history of thromboembolic events.
- Treatment with ZOLINZA can cause dose-related thrombocytopenia and anemia. If platelet counts and/or hemoglobin are reduced during treatment, modify the dose or discontinue therapy.
- Gastrointestinal (GI) disturbances (eg, nausea, vomiting, and diarrhea) may require antiemetics, antidiarrheals, and fluid and electrolyte replacement to prevent dehydration. Adequately control preexisting GI disturbances before beginning therapy with ZOLINZA.
- Based on reports of dehydration as a serious drug-related adverse event in clinical trials, instruct patients to drink at least 2 L/day of fluids for adequate hydration.
- Hyperglycemia has been observed. Monitor serum glucose, especially in diabetic or potentially diabetic patients. Adjustment of diet, therapy for increased glucose, or both may be necessary to prevent hyperglycemia.
- Monitor electrolytes at baseline and periodically during treatment. Hypokalemia or hypomagnesemia should be corrected before administering ZOLINZA.
- Severe thrombocytopenia and GI bleeding have been reported with concomitant use of ZOLINZA and other HDAC inhibitors (eg, valproic acid). Monitor platelet count every 2 weeks for the first 2 months.
- Carefully monitor patients concurrently administered ZOLINZA and coumarin derivatives for prolongation of prothrombin time and international normalized ratio.
- The most common adverse events observed in clinical trials with ZOLINZA, regardless of causality, were fatigue (52%), diarrhea (52%), nausea (41%), dysgeusia (28%), thrombocytopenia (26%), anorexia (24%), decreased weight (21%), and muscle spasms (20%).



Patients With Commercial Health Plan Coverage With Formulary Access to ZOLINZA



Commercial Health Plan Formulary Status^{2,a}

- Approximately 67% of people with private insurance are insured by Commercial Health Plans that have ZOLINZA on formulary.
- The majority of these Health Plans have ZOLINZA on Formulary Tiers 1, 2, or 3.

Copay distribution for these Commercial Health Plans³

• Overall, 79% of health plan approved claims have copay amounts less than \$50, and 65% are less than \$30.

Copay Level	Commercial
Jnder \$30	65%
\$31–\$50	14%
Over \$51	21%
Total	100%

Source: WKH claims data, October 2009 through September 2010; <30 days of supply.

ZOLINZA is an HDAC inhibitor indicated for treatment of cutaneous manifestations in patients with CTCL who have progressive, persistent, or recurrent disease on or following 2 systemic therapies.

Selected Important Safety Information (continued)

- The most common serious adverse events, regardless of causality, were pulmonary embolism (4.7%), squamous cell carcinoma (3.5%), and anemia (2.3%).
- ZOLINZA can cause fetal harm when administered to a pregnant woman.
- It is not known whether ZOLINZA is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or the drug.
- ZOLINZA was not evaluated in patients with hepatic impairment. Because ZOLINZA is predominantly eliminated through metabolism, treat patients with hepatic impairment with caution.

Before prescribing ZOLINZA, please read the accompanying Prescribing Information.

For additional copies of the Prescribing Information, call 800-672-6372, visit zolinza.com, or contact your Merck representative.

References: 1. Duvic M, Olsen EA, Breneman D, et al. Evaluation of the long-term relationship and clinical benefit of vorinostat in patients with advanced cutaneous T-cell lymphoma. *Clin Lymphoma Myeloma*. 2009;9(6):412-416. **2.** Data available on request from Merck, Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package ONCO-1006193-0000. **3.** Data available on request from Merck, Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package ONCO-1008631-0000.





^a Source: Fingertip Formulary 1/6/2011