TAZVERIK®
(tazemetostat) tablets
200 mg

UNSILENCE AN EXPRESSIVE INSTRUMENT

TAZVERIK® (tazemetostat) demonstrated meaningful and sustained responses for relapsed or refractory (R/R) follicular lymphoma (FL) patients, in both MT and WT *EZH2* populations[1]

NCCN recommended

Tazemetostat (TAZVERIK®) is included in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-cell Lymphomas with a category 2A recommendation as an option for appropriate patients with R/R FL.*

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TAZVERIK is indicated for the treatment of:

- Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies.
- Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.

These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).[1]

Important Safety Information

TAZVERIK increases the risk of developing secondary malignancies, including T-cell lymphoblastic lymphoma, myelodysplastic syndrome, and acute myeloid leukemia. Monitor patients long-term for the development of secondary malignancies.

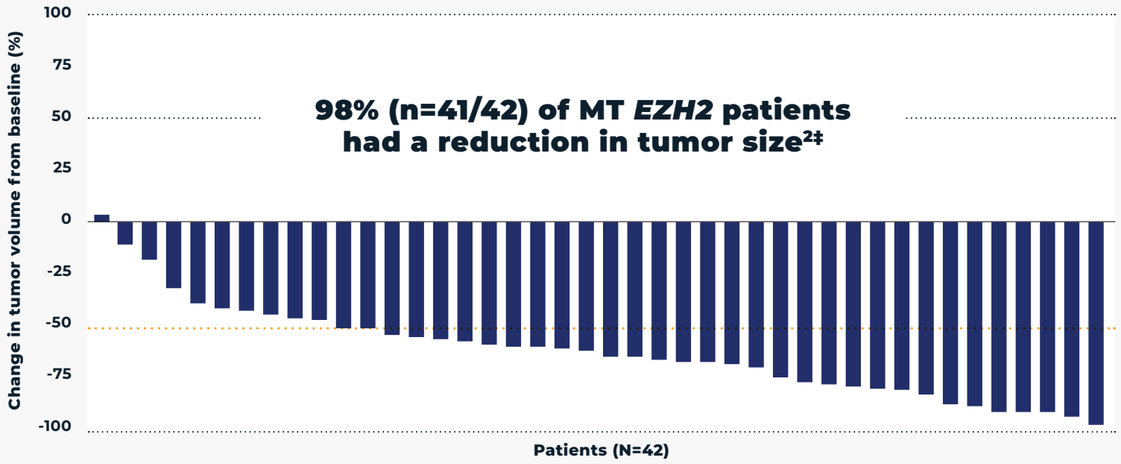
TAZVERIK can cause fetal harm. Advise patients of potential risk to a fetus and to use effective non-hormonal contraception.

The most common (≥20%) adverse reactions are fatigue, upper respiratory tract infection, musculoskeletal pain, nausea, and abdominal pain.

MT=mutant type; WT=wild type; EZH2=enhancer of zeste homologue 2.

Please see additional Important Safety Information on the following pages and refer to the full Prescribing Information.

TAZVERIK® (tazemetostat) DEMONSTRATED EFFICACY IN A HEAVILY PRETREATED POPULATION REGARDLESS OF EZH2 MUTATION STATUS[1,2*†]



The ORR included **12%** (n=5/42) of patients with a **complete response** and **57%** (n=24/42) with a **partial response.**[1,2]

69%
ORR
(n=29/42; 95% CI: 53%–82%)[1,9†]

10.9
months
median DOR

Sustained response[1,2*]
(range: 0.0+ to 22.1+; 95% CI: 7.2–NE)
The data for this cohort were not yet mature at the time of assessment.

ORR=overall response; CI=confidence interval; DOR=duration of response; NE=not estimable.

*TAZVERIK was studied in an open-label, single-arm, multicenter, phase 2 trial with 6 cohorts of patients, including 2 cohorts with histologically-confirmed R/R FL. Patients received 800 mg of TAZVERIK orally twice daily until confirmed disease progression or unacceptable toxicity. The major efficacy outcome measures were ORR and DOR according to the International Working Group Non-Hodgkin Lymphoma (IWG-NHL) criteria as assessed by independent review committee.[1,2]

†The median number of lines of prior systemic therapy in patients: 2 (range 1 to 11) MT *EZH2* and 3 (range 1 to 8) WT *EZH2*; patients refractory to rituximab: 49% MT *EZH2* and 59% WT *EZH2*; patients double refractory to rituximab and an alkylating agent: 20% MT *EZH2* and 28% WT *EZH2*; patients refractory to their last therapy: 49% MT *EZH2* and 41% WT *EZH2*; patients that had received prior stem cell transplant: 9% MT *EZH2* and 39% WT *EZH2*.[1,2]

‡The tumor size was measured based on the maximum reduction in the sum of the products of the perpendicular diameters.

Important Safety Information *(continued)*

Warnings and Precautions

• Secondary Malignancies

The risk of developing secondary malignancies is increased following treatment with TAZVERIK. Across clinical trials of 729 adults who received TAZVERIK 800 mg twice daily, myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML) occurred in 0.7% of patients. One pediatric patient developed T-cell lymphoblastic lymphoma (T-LBL). Monitor patients long-term for the development of secondary malignancies.

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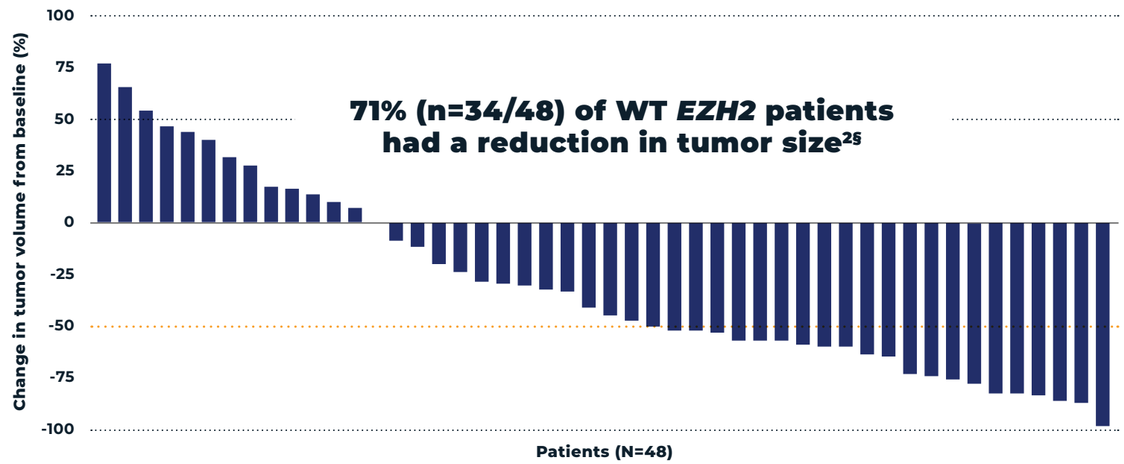
TAZVERIK® (tazemetostat) DEMONSTRATED EFFICACY IN A HEAVILY PRETREATED POPULATION REGARDLESS OF EZH2 MUTATION STATUS[1,2*†]



The ORR included **4%** (n=2/53) of patients with a **complete response** and **30%** (n=16/53) with a **partial response.**[1,2]

34%
ORR
(n=18/53; 95% CI: 22%–48%)[1,9†]

13.0
months
median DOR

Sustained response[1,2*]
(range: 1.0 to 22.5+; 95% CI: 5.6–NE)

§The tumor size was measured based on the maximum reduction in the sum of the products of the perpendicular diameters. Tumor response was unevaluable in 5 out of 53 WT EZH2 patients in the intent-to-treat population.

Important Safety Information *(continued)*

Warnings and Precautions

• Embryo-Fetal Toxicity

Based on findings from animal studies and its mechanism of action, TAZVERIK can cause fetal harm when administered to pregnant women. There are no available data on TAZVERIK use in pregnant women to inform the drug-associated risk. Administration of tazemetostat to pregnant rats and rabbits during organogenesis resulted in dose-dependent increases in skeletal developmental abnormalities in both species beginning at maternal exposures approximately 1.5 times the adult human exposure (area under the plasma concentration time curve [$AUC_{0\text{-}45h}$]) at the 800 mg twice daily dose.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TAZVERIK and for 6 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with TAZVERIK and for 3 months after the final dose.

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MAJORITY OF PATIENTS WERE ABLE TO STAY ON THE FULL DOSE OF TAZVERIK DURING THE TRIAL[1]

- Grade 3 or 4 adverse reactions occurred in ≤5% of patients which included fatigue (5%)*, urinary tract infection (2%)†, nausea (1%), abdominal pain (3%)‡, vomiting (1%), and musculoskeletal pain (1%).[1§]

of patients **permanently discontinued** treatment due to an adverse reaction. The adverse reaction resulting in permanent discontinuation in ≥2% of patients was second primary malignancy.[1]

of patients receiving TAZVERIK required **dose reductions** due to an adverse reaction.[1]

of patients receiving TAZVERIK required **dose interruptions** due to an adverse reaction. Adverse reactions requiring dosage interruptions in ≥3% of patients were thrombocytopenia and fatigue.[1]

*Includes fatigue and asthenia.
†Includes cystitis, urinary tract infection, urinary tract infection staphylococcal.
‡Includes abdominal discomfort, abdominal pain, abdominal pain lower, abdominal pain upper.
§Includes back pain, limb discomfort, musculoskeletal chest pain, musculoskeletal discomfort, musculoskeletal pain, myalgia, neck pain, non-cardiac chest pain, pain in extremity, pain in jaw, spinal pain.

Important Safety Information *(continued)*

Adverse Reactions

In 99 clinical study patients with relapsed or refractory follicular lymphoma receiving TAZVERIK 800 mg twice daily: Serious adverse reactions occurred in 30% of patients who received TAZVERIK. Serious adverse reactions occurring in ≥2% were general physical health deterioration, abdominal pain, pneumonia, sepsis, and anemia. The most common (≥20%) adverse reactions were fatigue (36%), upper respiratory tract infection (30%), musculoskeletal pain (22%), nausea (24%), and abdominal pain (20%).

Drug Interactions

Avoid coadministration of strong or moderate CYP3A inhibitors with TAZVERIK. If coadministration of moderate CYP3A inhibitors cannot be avoided, reduce TAZVERIK dose.

Avoid coadministration of moderate and strong CYP3A inducers with TAZVERIK, which may decrease the efficacy of TAZVERIK.

Coadministration of TAZVERIK with CYP3A substrates, including hormonal contraceptives, can result in decreased concentrations and reduced efficacy of CYP3A substrates.

Lactation

Because of the potential risk for serious adverse reactions from TAZVERIK in the breastfed child, advise women not to breastfeed during treatment with TAZVERIK and for one week after the final dose.

References: 1. TAZVERIK (tazemetostat) Prescribing Information. Cambridge, MA: Epizyme, Inc., July 2020. **2.** Data on file. **3.** Morschhauser F, Tilly H, Chaidos A, et al. Tazemetostat for patients with relapsed or refractory follicular lymphoma: an open-label, single-arm, multicentre, phase 2 trial. *Lancet Oncol.* 2020;21(11):1433-1442.

Please see additional Important Safety Information throughout this piece and refer to the full Prescribing Information.

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Epizyme®

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