

Tazemetostat (TAZVERIK®) is included in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-cell Lymphomas

With a NCCN category 2A recommendation as an option for appropriate patients with R/R FL.¹

NCCN Guidelines® Include Tazemetostat for Follicular Lymphoma†

INDICATIONS

TAZVERIK is indicated for the treatment of:

- Adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) 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).²

SELECT IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Secondary Malignancies:** TAZVERIK increases the risk of developing secondary malignancies, including T-cell lymphoblastic lymphoma, myelodysplastic syndrome, acute myeloid leukemia, and B-cell acute lymphoblastic leukemia. Monitor patients long-term for the development of secondary malignancies.
- Embryo-Fetal Toxicity:** TAZVERIK can cause fetal harm. Advise patients of potential risk to a fetus and to use effective non-hormonal contraception.

Adverse Reactions

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

Please see additional Important Safety Information on reverse side and full Prescribing Information

SECOND-LINE THERAPY FOR OLDER OR INFIRM
(if none of the therapies are expected to be tolerable in the opinion of treating physician)

Preferred regimens

- Rituximab (375 mg/m² weekly for 4 doses)
- Tazemetostat (irrespective of *EZH2* mutation status)

Other recommended regimen

- Cyclophosphamide ± rituximab

THIRD-LINE AND SUBSEQUENT THERAPY

Subsequent systemic therapy options include second-line therapy regimens that were not previously given.

Preferred regimens (in alphabetical order)

- T-cell engager therapy
 - Bispecific antibody therapy[‡]
 - Epcoritamab-bysp
 - Mosunetuzumab-axgb
 - Chimeric antigen receptor (CAR) T-cell therapy
 - Axicabtagene ciloleucel (CD19-directed)
 - Lisocabtagene maraleucel (CD19-directed)
 - Tisagenlecleucel (CD19-directed)

Other recommended regimens

- EZH2* inhibitor
 - Tazemetostat (irrespective of *EZH2* mutation status)
- BTK inhibitor (BTKi)
 - Zanubrutinib + obinutuzumab
- Loncastuximab tesirine-Ipyl + rituximab (category 2B)

The above table is an excerpt from the NCCN Guidelines on FL second-line and third-line therapy.

NCCN Guidelines develops evidence-based recommendations that may or may not align to the FDA-approved labeling. TAZVERIK is FDA-approved in adults with R/R FL:

- With no satisfactory alternative treatment options
- In third line and beyond in adults with satisfactory alternatives, for patients with *EZH2* mutation only

EZH2=enhancer of zeste homolog 2; *FL*=follicular lymphoma; *mAb*=monoclonal antibody; *NCCN*=National Comprehensive Cancer Network; *R/R*=relapsed or refractory.

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[‡]In the setting of CD20-negative lymphomas, the activity of CD3 x CD20 bispecific antibody therapy is unclear. Rebiopsy to confirm CD20 positivity is recommended prior to initiating CD3 x CD20 bispecific antibody therapy.

IMPORTANT SAFETY INFORMATION



Warnings and Precautions

• Secondary Malignancies

The risk of developing secondary malignancies is increased following treatment with TAZVERIK. Across clinical trials of 758 adults who received TAZVERIK 800 mg twice daily as monotherapy, myelodysplastic syndrome (MDS), acute myeloid leukemia (AML), or B-cell acute lymphoblastic leukemia (B-ALL) occurred in 1.7% of patients. One pediatric patient developed T-cell lymphoblastic lymphoma (T-LBL). Monitor patients long-term for the development of secondary malignancies.

• 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_{0-45h}]) 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.

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 $\geq 2\%$ were general physical health deterioration, abdominal pain, pneumonia, sepsis, and anemia. The most common ($\geq 20\%$) 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 strong or moderate CYP3A inhibitors cannot be avoided, reduce TAZVERIK dose.

Avoid coadministration of moderate or 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.

To report SUSPECTED ADVERSE REACTIONS, contact Ipsen Biopharmaceuticals, Inc. at 1-855-463-5127 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see accompanying full Prescribing Information

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