

## INDICATION

TIBSOVO is indicated for patients with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma who have been previously treated.

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

**QTc Interval Prolongation:** Patients treated with TIBSOVO can develop QT (QTc) prolongation and ventricular arrhythmias. Concomitant use of TIBSOVO with drugs known to prolong the QTc interval (eg, anti-arrhythmic medicines, fluoroquinolones, triazole anti-fungals, 5-HT<sub>3</sub> receptor antagonists) and CYP3A4 inhibitors may increase the risk of QTc interval prolongation. Conduct monitoring of electrocardiograms (ECGs) and electrolytes. In patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval, more frequent monitoring may be necessary.

Interrupt TIBSOVO if QTc increases to greater than 480 msec and less than 500 msec. Interrupt and reduce TIBSOVO if QTc increases to greater than 500 msec. Permanently discontinue TIBSOVO in patients who develop QTc interval prolongation with signs or symptoms of life-threatening arrhythmia.

**Guillain-Barré Syndrome:** Guillain-Barré syndrome can develop in patients treated with TIBSOVO. Monitor patients taking TIBSOVO for onset of new signs or symptoms of motor and/or sensory neuropathy such as unilateral or bilateral weakness, sensory alterations, paresthesias, or difficulty breathing. Permanently discontinue TIBSOVO in patients who are diagnosed with Guillain-Barré syndrome.

### ADVERSE REACTIONS

- In patients with cholangiocarcinoma, the most common adverse reactions (≥15%) were fatigue, nausea, abdominal pain, diarrhea, cough, decreased appetite, ascites, vomiting, anemia, and rash. The most common laboratory abnormalities (≥10%) were hemoglobin decreased, aspartate aminotransferase increased, and bilirubin increased.

### DRUG INTERACTIONS

**Strong or Moderate CYP3A4 Inhibitors:** Reduce TIBSOVO dose with strong CYP3A4 inhibitors. Monitor patients for increased risk of QTc interval prolongation.

**Strong CYP3A4 Inducers:** Avoid concomitant use with TIBSOVO.

**Sensitive CYP3A4 Substrates:** Avoid concomitant use with TIBSOVO.

**QTc Prolonging Drugs:** Avoid concomitant use with TIBSOVO. If co-administration is unavoidable, monitor patients for increased risk of QTc interval prolongation.

### LACTATION

Advise women not to breastfeed.

Please see **Full Prescribing Information**.