HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use JIDEYTRO safely and effectively. See full prescribing information for JIDEYTRO.

JIDEYTRO ™ (zidesamtinib) tablets, for oral use
Initial U.S. Approval: 2026

----------INDICATIONS AND USAGE----------
JIDEYTRO is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*-positive non-small cell lung cancer (NSCLC) who received a prior ROS1 kinase inhibitor. (1)

----------DOSAGE AND ADMINISTRATION----------
- Recommended Dosage: 100 mg orally once daily with or without food until disease progression or unacceptable toxicity. (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
Tablets: 25 mg and 100 mg (3)

----------CONTRAINDICATIONS----------
None.

----------WARNINGS AND PRECAUTIONS----------
- Central Nervous System (CNS) Adverse Reactions (AR): Can cause CNS AR including dizziness, ataxia, cognitive and psychiatric disorders. Based on severity, withhold JIDEYTRO and resume at same or reduced dose, or permanently discontinue. (5.1)
- QTc Interval Prolongation: Can cause QTc prolongation. Evaluate ECGs and electrolytes prior to administration of JIDEYTRO and monitor periodically during treatment. Based on severity, withhold JIDEYTRO and resume at the same or reduced dose, or permanently discontinue. (5.2)
- Interstitial Lung Disease (ILD)/pneumonitis: Can cause ILD/pneumonitis. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold in patients with suspected ILD/pneumonitis. Based on severity, withhold JIDEYTRO and resume at the same or reduced dose, or permanently discontinue. (5.3)
- Skeletal Fractures: Can cause skeletal fractures. Promptly evaluate patients with signs or symptoms of fractures. (5.4)
- Myalgia with Creatine Phosphokinase (CPK) Elevation: Can cause CPK elevation. Advise patients to report unexplained muscle pain or tenderness. Monitor serum CPK levels during treatment. Based on severity, withhold JIDEYTRO and resume at same or reduced dose upon recovery to baseline. (5.5)
- Pancreatic Toxicity: Evaluate amylase and lipase prior to administration of JIDEYTRO and monitor periodically during treatment. Withhold, dose reduce or permanently discontinue JIDEYTRO based on severity. (5.6)
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception. (5.7)

----------ADVERSE REACTIONS----------
Most common adverse reactions (≥15%) were: edema, peripheral neuropathy, constipation, fatigue, and dyspnea. (6.1)
Most common Grade 3 or 4 laboratory abnormalities (≥2%) were: increased CPK, increased triglycerides, decreased lymphocytes and decreased hemoglobin. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Nuvalent, Inc. at toll-free phone 1-844-NUVL-111 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Strong and Moderate CYP3A Inhibitors: Avoid concomitant use. (7.1)
- Strong and Moderate CYP3A Inducers: Avoid concomitant use. (7.1)

----------USE IN SPECIFIC POPULATIONS----------
- Lactation: Advise not to breastfeed. (8.2)
- Infertility: May impair fertility. (8.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 7/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

JIDEYTRO is indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who received a prior ROS1 kinase inhibitor *[see Dosage and Administration (2.1), Clinical Studies (14.1)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Testing and Evaluation Before Initiating JIDEYTRO

Before initiating JIDEYTRO, evaluate creatine phosphokinase (CPK) level, electrocardiogram (ECG), electrolytes, lipase and amylase *[see Warnings and Precautions (5.2, 5.5, 5.6)]*.

2.2 Recommended Dosage

The recommended dosage of JIDEYTRO is 100 mg taken orally once daily, with or without food, until disease progression or unacceptable toxicity *[see Clinical Pharmacology (12.3)]*.

Swallow JIDEYTRO tablets whole. Do not split, chew, crush, or dissolve the tablet prior to swallowing.

Missed Dose

If a dose of JIDEYTRO is missed within 12 hours of the regularly scheduled dose, administer the missed dose as soon as possible. If a dose is missed by 12 hours or more, take the next dose at its scheduled time.

Vomiting

If vomiting occurs at any time after taking JIDEYTRO, take the next dose at its scheduled time.

2.3 Dosage Modifications of JIDEYTRO for Adverse Reactions

The recommended dosage reductions of JIDEYTRO for the management of adverse reactions are provided in Table 1.

Table 1: Recommended Dose Reductions for JIDEYTRO Adverse Reactions

Dose Reduction	Recommended Dose and Schedule
First	75 mg once daily
Second	50 mg once daily
Permanently discontinue JIDEYTRO in patients unable to tolerate 50 mg once daily. After dose reduction of JIDEYTRO for adverse reactions, do not re-escalate the dose.	

The recommended dosage modifications of JIDEYTRO for the management of adverse reactions are provided in Table 2.

Table 2: Recommended Dosage Modifications of JIDEYTRO for Adverse Reactions

Adverse Reaction	Severity*	Dosage Modification
Central Nervous System Adverse Reactions *[see Warnings and Precautions (5.1)]*	Intolerable Grade 2	• Withhold JIDEYTRO until Grade ≤ 1 or baseline. • Resume JIDEYTRO at same or reduced dose, as clinically appropriate.
	Grade 3	• Withhold JIDEYTRO until Grade ≤ 1 or baseline. • Resume JIDEYTRO at reduced dose.
	Grade 4	• Permanently discontinue JIDEYTRO.
QTc Interval Prolongation [see Warnings and Precautions (5.2)]	Grade 2 (QTc interval 481-500 msec)	• Withhold JIDEYTRO until recovery to Grade ≤ 1 or baseline. • Correct electrolytes and/or change concomitant medications. • Resume JIDEYTRO at same dose.

Adverse Reaction	Severity*	Dosage Modification
	Grade 3 (QTc interval ≥501 msec or QTc interval increase of >60 msec from baseline)	• Withhold JIDEYTRO until recovery to Grade ≤ 1 or baseline. • Correct electrolytes and/or change concomitant medications. • Resume JIDEYTRO at a reduced dose.
	Grade 4 (Torsade de pointes; polymorphic ventricular tachycardia; signs/symptoms of serious arrhythmia)	• Permanently discontinue JIDEYTRO.
Interstitial Lung Disease (ILD)/Pneumonitis *[see Warnings and Precautions (5.3)]*	Grade 1	• Withhold JIDEYTRO if ILD/pneumonitis occurs or is suspected until recovery to Grade 0. • If resolved within 6 weeks, resume JIDEYTRO at the same dose. • If unresolved after 6 weeks, permanently discontinue JIDEYTRO. Recurrence: • Permanently discontinue JIDEYTRO.
	Grade 2	• Withhold JIDEYTRO if ILD/pneumonitis occurs or is suspected until recovery to Grade 0 or baseline. • If resolved within 6 weeks, resume JIDEYTRO at a reduced dose. • If unresolved after 6 weeks, permanently discontinue JIDEYTRO. Recurrence: • Permanently discontinue JIDEYTRO.
	Grade 3 or 4	• Permanently discontinue JIDEYTRO.
Creatine Phosphokinase (CPK) Elevation *[see Warnings and Precautions (5.5)]*	CPK elevation > 5 times ULN	• Withhold JIDEYTRO until recovery to baseline or ≤ 2.5 times ULN, then resume JIDEYTRO at same dose.
	CPK elevation > 10 times ULN or Recurrence of CPK elevation of >5 times ULN	• Withhold until recovery to baseline or ≤2.5 times ULN, then resume JIDEYTRO at a reduced dose.
Increased lipase or amylase *[see Warnings and Precautions (5.6)]*	Grade 3	• Withhold JIDEYTRO until Grade ≤ 2 or baseline. • If recovered to baseline or Grade ≤ 2 within 14 days, resume JIDEYTRO at a reduced dose; otherwise permanently discontinue JIDEYTRO.
	Grade 4	• Permanently discontinue JIDEYTRO.
Pancreatitis *[see Warnings and Precautions (5.6)]*	Grade 3 or Grade 4	• Permanently discontinue JIDEYTRO.
Other Adverse Reactions *[see Adverse Reactions (6.1)]*	Intolerable Grade 2 or Grade 3 or Grade 4	• Withhold JIDEYTRO until Grade ≤ 1 or baseline. • If resolution occurs within 4 weeks, resume JIDEYTRO at the same dose for intolerable Grade 2 or Grade 3 adverse reactions. • If resolution occurs within 4 weeks, resume JIDEYTRO at the next lower dose for Grade 4 adverse reactions. • Permanently discontinue JIDEYTRO if adverse reaction does not resolve within 4 weeks.

Adverse Reaction	Severity*	Dosage Modification
		• Permanently discontinue JIDEYTRO for recurrent Grade 4 events.

*Graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.0.

3 DOSAGE FORMS AND STRENGTHS

Tablets: 25 mg: pink, oblong, film-coated, debossed with “25” on one side and “ZDS” on the other side.

Tablets: 100 mg: yellow, oblong, film-coated, debossed with “100” on one side and “ZDS” on the other side.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Central Nervous System Adverse Reactions

JIDEYTRO can cause central nervous system adverse reactions.

In the pooled safety population *[see Adverse Reactions (6.1)]*, a broad spectrum of central nervous system (CNS) adverse reactions, including dizziness, ataxia, cognitive and psychiatric disorders, occurred in 25% of patients who received JIDEYTRO; of these, 2.5% were Grade 3 or 4. One patient (0.2%) with brain metastases experienced a Grade 3 seizure.

Dizziness, including vertigo, presyncope and positional dizziness occurred in 12% of patients who received JIDEYTRO; of these 0.2% were Grade 3. The median time to onset of dizziness was 22 days (range: 1 day to 9 months). Dosage interruption of JIDEYTRO for dizziness was required in 0.4% of patients, and 0.7% of patients required dose reduction.

Ataxia, including gait disturbance and balance disorder, occurred in 2% of patients who received JIDEYTRO and were all Grade 1 or 2. The median time to onset of ataxia was 64 days (range: 6 days to 2.5 years).

Cognitive impairment occurred in 9% of patients who received JIDEYTRO, of these 1.6% were Grade 3 or 4. Cognitive impairment included memory impairment (3.1%), cognitive disorder (1.6%), hallucination (1.1%), delirium (1.1%), aphasia (0.9%), amnesia (0.7%), confusional state (0.7%), anterograde amnesia (0.2%), disturbance in attention (0.4%), slow speech (0.2%). The median time to onset of cognitive impairment was 43 days (range: 4 days to 1.9 years). Dose interruption of JIDEYTRO for cognitive impairment was required in 1.3% of patients.

Psychiatric disorders occurred in 6% of patients who received JIDEYTRO, of these 0.7% were Grade 3 or 4. Psychiatric disorders included anxiety (3.1%), depression (1.3%), agitation (0.7%), affect lability (0.4%), irritability (0.4%), abnormal behavior (0.2%), depressed mood (0.2%), personality change (0.2%), psychotic disorder (0.2%), and suicidal ideation (0.2%). The median time to onset of psychiatric disorders was 57 days (range: 1 day to 10 months). Dosage interruption of JIDEYTRO for psychiatric disorders was required in 0.9% of patients. Advise patients and caregivers of the risk of CNS adverse reactions with JIDEYTRO. Advise patients to avoid engaging in hazardous tasks requiring mental alertness and motor coordination such as operating machinery or driving a motor vehicle if they are experiencing CNS reactions. Monitor patients for CNS adverse reactions and suicidal thoughts and behaviors during treatment with JIDEYTRO. Withhold and then resume at the same or reduced dose upon improvement or permanently discontinue JIDEYTRO based on severity *[see Dosage and Administration (2.3)]*.

5.2 QTc Interval Prolongation

JIDEYTRO can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death. JIDEYTRO has not been studied in patients with a history of QTcF >450 msec on more than one assessment prior to initiation.

In the pooled safety population *[see Adverse Reactions (6.1)],* of the 435 patients who underwent at least one post baseline electrocardiogram (ECG) assessment, 2% experienced an increase in QTcF of >60 msec compared to baseline after receiving JIDEYTRO and 0.2% increase in QTcF to >500 msec. The median time from the first dose of JIDEYTRO to the onset of QTc prolongation was 15 days (range: 1 day to approximately 1 month). QTc prolongation led to dose interruption in 0.4% of patients who received JIDEYTRO.

Evaluate ECGs and electrolytes prior to administration of JIDEYTRO and monitor periodically during treatment. Adjust the frequency of monitoring based on risk factors such as known long QT syndromes, clinically significant bradyarrhythmias, severe or uncontrolled heart failure, and concomitant medications associated with QTc interval prolongation. Withhold, then resume at the same or reduced dose, or permanently discontinue JIDEYTRO based on severity *[see Dosage and Administration (2.3)].*

5.3 Interstitial Lung Disease/Pneumonitis

JIDEYTRO can cause severe or life-threatening interstitial lung disease (ILD) or pneumonitis.

In the pooled safety population *[see Adverse Reactions (6.1)]*, interstitial lung disease (ILD)/pneumonitis occurred in 1.8% of patients treated with JIDEYTRO, including Grade 3 or 4 in 0.4%. The median time to first onset of ILD/pneumonitis was 4.5 months (range: 8 days to 11 months).

ILD/pneumonitis led to dose interruption of JIDEYTRO in 0.7% of patients. ILD/pneumonitis required dose reduction in 0.2% of patients and permanent discontinuation of JIDEYTRO in 0.4% of patients.

Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold JIDEYTRO in patients with suspected ILD/pneumonitis, then upon recovery resume at the same or reduced dose or permanently discontinue based on severity *[see Dosage and Administration (2.3)].*

5.4 Skeletal Fractures

JIDEYTRO can increase the risk of skeletal fractures.

In the pooled safety population *[see Adverse Reactions (6.1)]*, 5 patients (1.1%) experienced skeletal fractures, and Grade 3 ankle fractures occurred in two patients (0.4%) who received JIDEYTRO. Some fractures occurred in the setting of an accidental fall or other predisposing factors such as osteoporosis, bone metastasis, and age-related degenerative conditions. The median time to fracture was 48 days (range: 32 days to approximately 6 months). JIDEYTRO was interrupted in 0.4% of patients for fractures.

5.5 Myalgia with Creatine Phosphokinase Elevation

JIDEYTRO can cause myalgia with creatine phosphokinase (CPK) elevation.

In the pooled safety population *[see Adverse Reactions (6.1)]*, myalgia occurred in 13% of patients who received JIDEYTRO. Based on laboratory values, concurrent myalgia with increased CPK occurred in 2.1% of patients. The median time to onset of myalgia for these patients with CPK elevation was 2 months (range: 8 days to 6 months).

Advise patients to report unexplained muscle pain or tenderness. Monitor serum CPK levels prior to administration of JIDEYTRO and every 2 weeks during the first month of treatment and then every 1 to 2 months and as clinically indicated in patients reporting unexplained muscle pain or tenderness. Withhold, then resume at the same or reduced dose, or permanently discontinue JIDEYTRO based on severity *[see Dosage and Administration (2.3)].*

5.6 Pancreatic Toxicity

JIDEYTRO can cause pancreatic toxicity.

In the pooled safety population *[see Adverse Reactions (6.1)],* among the subgroup of patients who underwent pancreatic lab testing, increased amylase occurred in 22% and increased lipase occurred in 25% of patients treated with JIDEYTRO. Grade 3 increased lipase occurred in 8% of these patients. Grade 3 lipase elevation resulted in JIDEYTRO dose reduction in one patient. The median time-to-onset of Grade 3 increased lipase was

143 days (range: 28 to 249 days). In the pooled safety population *[see Adverse Reactions (6.1)]*, Grade 3 pancreatitis occurred in one patient (0.2%) treated with JIDEYTRO.

Evaluate amylase and lipase prior to administration of JIDEYTRO and monitor periodically during treatment. Based on the severity of the adverse reaction, temporarily withhold, reduce the dose, or permanently discontinue JIDEYTRO *[see Dosage and Administration (2.3)]*.

5.7 Embryo-Fetal Toxicity

Based on literature reports in humans with congenital mutations leading to changes in tropomyosin receptor kinase (TRK) signaling, findings from animal studies and its mechanism of action, JIDEYTRO can cause fetal harm when administered to a pregnant woman.

In an animal reproduction study, oral administration of zidesamtinib to pregnant rats during the period of organogenesis resulted in embryo-fetal mortality, alterations to growth, and structural abnormalities at maternal exposures approximately equivalent to the human exposure at the recommended dose based on area under the curve (AUC).

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 3 months after the last dose [see *Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Central Nervous System Adverse Reactions *[see Warnings and Precautions (5.1)]*
- QTc Interval Prolongation *[see Warnings and Precautions (5.2)]*
- Interstitial Lung Disease/Pneumonitis *[see Warnings and Precautions (5.3)]*
- Skeletal Fractures *[see Warnings and Precautions (5.4)]*
- Myalgia with Creatine Phosphokinase Elevation *[see Warnings and Precautions (5.5)]*
- Pancreatic Toxicity *[see Warnings and Precautions (5.6)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The pooled safety population described in WARNINGS AND PRECAUTIONS reflects exposure to JIDEYTRO in 446 patients with ROS1-positive NSCLC (n=432) and other solid tumors (n=14) who received JIDEYTRO at a dose of 100 mg orally once daily until disease progression or unacceptable toxicity in ARROS-1 [*see Clinical Studies (14.1)*]. Among 446 patients who received JIDEYTRO, 44% were exposed for 6 months or longer and 14% were exposed for greater than one year. In this pooled safety population, the most common (≥15%) adverse reactions included: edema (38%), peripheral neuropathy (25%), constipation (17%), fatigue (16%), dyspnea (15%). The most common Grade 3 or 4 laboratory abnormalities (≥2%), were increased lipase (8%), increased creatine phosphokinase (CPK) (4%), increased triglycerides (3.5%), decreased lymphocytes (2.7%), and decreased hemoglobin (2.3%).

Previously Treated ROS1-positive NSCLC

The safety of JIDEYTRO was evaluated in ARROS-1 *[see Clinical Studies (14.1)]*. Patients received JIDEYTRO 100 mg orally once daily until disease progression or unacceptable toxicity. Among the 432

patients who received JIDEYTRO, 44% were exposed to JIDEYTRO for 6 months or longer, and 15% were exposed for greater than 1 year.

The median age of patients who received JIDEYTRO was 58 years (range: 26 to 87); 62% female; 41% White, 41% Asian, 3.7% Black or African American, 0.2% American Indian or Alaska Native, 14% other races, multiple races or race unknown, and 4.6% of patients were of Hispanic or Latino ethnicity.

Serious adverse reactions occurred in 22% of patients who received JIDEYTRO. Serious adverse reactions in ≥2% of patients included pneumonia (6%) and dyspnea (2.5%). Fatal adverse reactions occurred in 2.3% of patients who received JIDEYTRO, including pneumonia (0.5%), cerebrovascular accident (0.2%), COVID-19 (0.2%), dyspnea (0.2%), infectious pleural effusion (0.2%), influenza (0.2%), myocardial infarction (0.2%), myocarditis (0.2%), and respiratory failure (0.2%).

Permanent discontinuation of JIDEYTRO due to an adverse reaction occurred in 2.3% of patients. Adverse reactions resulting in permanent discontinuation of JIDEYTRO occurring in ≥2 patients were pneumonia (0.7%) and pneumonitis (0.5%).

Dosage interruptions of JIDEYTRO due to an adverse reaction occurred in 30% of patients. Adverse reactions which required dosage interruption in ≥1% of patients included pneumonia (4.6%), increased creatine phosphokinase level (3.0%), peripheral neuropathy (1.9%), peripheral edema (1.6%), COVID-19 (1.4%), and dyspnea and elevated alanine aminotransferase level (each in 1.2%).

Dose reductions of JIDEYTRO due to an adverse reaction occurred in 10% of patients. Adverse reactions which required dosage reduction in ≥1% of patients included peripheral edema (1.9%) and peripheral neuropathy (1.2%).

Table 3 summarizes the adverse reactions that occurred in the ARROS-1 trial.

Table 3: Adverse Reactions (≥10%) in Patients with ROS1-Positive NSCLC Who Received JIDEYTRO in ARROS-1

Adverse Reaction[1]	JIDEYTRO N=432	
	All Grades (%)	Grade 3 or 4 (%)
General Disorders		
Edema*	38	0.7
Fatigue*	16	0.7
Nervous System Disorders		
Peripheral neuropathy*	25	0.9
Dysgeusia*	15	0
Dizziness*	12	0.2
Headache	12	0.2
Gastrointestinal disorders		
Constipation	17	0
Diarrhea*	11	0.5
Respiratory, thoracic, and mediastinal disorders		
Dyspnea*	15	3
Cough*	13	0
Musculoskeletal and connective tissue disorders		
Myalgia*	13	0
Arthralgia	11	0.7
Skin and subcutaneous tissue disorders		
Rash*	12	0.5
Eye disorders		
Vision disorders*	12	0

Adverse Reaction[1]	JIDEYTRO N=432	
	All Grades (%)	Grade 3 or 4 (%)
Infections		
Pneumonia*	11	6

1 Based on NCI CTCAE v5.0
*Grouped term

Clinically relevant adverse reactions in <10% of patients receiving JIDEYTRO were cognitive disorders, psychiatric disorders, stomatitis, ataxia, ILD/pneumonitis, QTc prolongation, pancreatitis, and ankle fracture.

Table 4 summarizes the laboratory abnormalities in ARROS-1.

Table 4: Laboratory Abnormalities (≥20%) That Worsened from Baseline in Patients with ROS1-Positive NSCLC Who Received JIDEYTRO in ARROS-1

Laboratory Abnormality[1]	JIDEYTRO[2]	
	All Grades (%)	Grade 3 or 4 (%)
Lipid Profile		
Cholesterol increased	47	1.5
Triglycerides increased	47	3.7
Chemistry		
Creatine phosphokinase increased	37	4
Aspartate aminotransferase increased	30	0.9
Lipase increased	26	8
Alanine aminotransferase increased	23	1.2
Amylase increased	23	0
Alkaline phosphatase increased	21	0
Hematology		
Hemoglobin decreased	30	2.1
Eosinophils increased	27	0

[1]Based on NCI CTCAE v5.0
[2]The denominator used to calculate the rate varied from 37 to 429 based on the number of patients with a baseline value and at least one post-baseline treatment value.

7 DRUG INTERACTIONS

7.1 Effect of Other Drugs on JIDEYTRO

Strong and Moderate CYP3A Inhibitors

Avoid concomitant use of JIDEYTRO with a strong or moderate CYP3A inhibitor.

Zidesamtinib is a CYP3A substrate. Concomitant use with a strong or moderate CYP3A inhibitor increases zidesamtinib exposure *[see Clinical Pharmacology (12.3)]*, which may increase the risk of JIDEYTRO adverse reactions.

Strong and Moderate CYP3A Inducers

Avoid concomitant use of JIDEYTRO with strong or moderate CYP3A inducers.

Concomitant use of JIDEYTRO with a strong or moderate CYP3A inducer may decrease zidesamtinib exposure *[see Clinical Pharmacology (12.3)],* which may decrease the effectiveness of JIDEYTRO.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on literature reports in humans with congenital mutations leading to changes in TRK signaling, findings from animal studies and its mechanism of action *[see Clinical Pharmacology (12.1)]*, JIDEYTRO can cause

fetal harm when administered to a pregnant woman. There are no available data on JIDEYTRO use in pregnant women to inform a drug-associated risk. Oral administration of zidesamtinib to pregnant rats during the period of organogenesis resulted in embryo-fetal mortality, alterations to growth, and structural abnormalities at maternal exposures approximately equivalent to the human exposure at the recommended dose based on AUC (*see Data*). Advise pregnant women of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Human Data

Published reports of individuals with congenital mutations in TRK pathway proteins suggest that decreases in TRK mediated signaling are correlated with obesity, developmental delays, cognitive impairment, insensitivity to pain, and anhidrosis.

Animal Data

In an embryo-fetal development study, pregnant rats received oral doses of 3, 8, or 30 mg/kg/day of zidesamtinib during the period of organogenesis (gestation day 6 to 17). Zidesamtinib caused decreased fetal body weight, visceral malformations (absent kidneys and ureter), and an increase in the incidence of skeletal variations, including misshapen sternebra and cervical arch and incomplete ossification of the sternebra and thoracic centrum at 3 mg/kg/day (approximately 1.4 times the human exposure at the recommended dose based on AUC). Zidesamtinib resulted in complete litter resorption (post-implantation loss) at doses ≥8 mg/kg/day (approximately ≥3.5 times the human exposure at the recommended dose based on AUC).

8.2 Lactation

Risk Summary

There are no data on the presence of zidesamtinib or its metabolites in human milk or their effects on a breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with JIDEYTRO and for 1 week after the last dose.

8.3 Females and Males of Reproductive Potential

JIDEYTRO can cause fetal harm when administered to a pregnant woman [*see Use in Specific Populations (8.1)*].

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiating JIDEYTRO *[see Use in Specific Populations (8.1)]*.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 6 months after the last dose.

Males

Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 3 months after the last dose *[see Nonclinical Toxicology (13.1)]*.

Infertility

Based on findings from animal studies, JIDEYTRO may impair fertility in males and females. The effects on male fertility were reversible. The reversibility of the effect on fertility in females is unknown *[see Nonclinical Toxicology (13.1)]*.

8.4 Pediatric Use

The safety and effectiveness of JIDEYTRO in pediatric patients has not been established.

Juvenile Animal Data

Daily oral administration of zidesamtinib to juvenile rats from postnatal day 7 to 28 (approximately equal to a human pediatric age of a neonate to child) resulted in ocular toxicity, including hemorrhage, corneal ulcers, rupture, and vision loss at 8 mg/kg/day (approximately 2.4 times the human exposure based on AUC at the recommended dose).

8.5 Geriatric Use

Of the 446 patients who received JIDEYTRO, 22% were 65 to 74 years old, and 8% were 75 years of age or older. There were no clinically meaningful differences in safety and efficacy between patients younger than 65 years of age and patients 65 years of age or older.

8.6 Renal Impairment

The effect of severe renal impairment (eGFR <30 mL/min) or dialysis on zidesamtinib pharmacokinetics is unknown.

No dosage modification is recommended for patients with eGFR 30 to 90 mL/min *[see Clinical Pharmacology (12.3)]*.

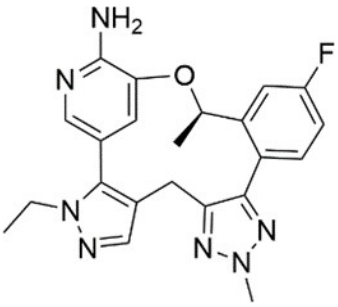
8.7 Hepatic Impairment

The effect of severe hepatic impairment (total bilirubin >3 times ULN with any AST) on the zidesamtinib pharmacokinetics is unknown.

No dosage modification is recommended for patients with mild (total bilirubin >1 to 1.5 times ULN or AST > ULN) or moderate (total bilirubin >1.5 to 3 times ULN with any AST) hepatic impairment *[see Clinical Pharmacology (12.3)]*.

11 DESCRIPTION

Zidesamtinib is a kinase inhibitor. The molecular formula for zidesamtinib is $C_{22}H_{22}FN_7O$ and the molecular weight is 419.46 Daltons. The chemical name is (*R*)-3-Ethyl-16-fluoro-10-methyl-19-methyl-20-oxa-3,4,9,10,11,23-hexaazapentacyclo[19.3.1.$0^{2,6}$.$0^{8,12}$.$0^{13,18}$]pentacosa-1(24),2(6),4,8,11,13,15,17,21(25),22-decaen-22-ylamine. The chemical structure of zidesamtinib is as follows:



Zidesamtinib is a white to tan powder with a pKa of 4.89. The aqueous solubility of zidesamtinib at 37°C is pH dependent, decreasing from 25 mg/mL at pH 2.5 to less than 0.1 mg/mL at pH 7.9. The log of the distribution coefficient (octanol/water) at pH 7.4 is 3.01.

JIDEYTRO (zidesamtinib) tablets for oral use are supplied as 25 mg and 100 mg dosage strengths. JIDEYTRO tablets, 25 mg are film-coated, oblong, pink tablets, debossed with “25” on one side and “ZDS” on the other side of the tablet. JIDEYTRO tablets, 100 mg are film-coated, oblong, yellow tablets, debossed with “100” on one side and “ZDS” on the other side of the tablet. Inactive ingredients in the tablet core are hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose and sodium starch glycolate.

The 25 mg tablet pink film coating contains the inactive ingredients hypromellose, red iron oxide, titanium dioxide, triacetin, and yellow iron oxide. The 100 mg tablet yellow film coating contains the inactive ingredients hypromellose, titanium dioxide, triacetin, and yellow iron oxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Zidesamtinib is an inhibitor of tyrosine kinase ROS1, including ROS1 resistance mutations. In a biochemical assay, zidesamtinib inhibited ROS1 (IC_{50} = 0.7 nM) and also showed inhibitory effects on ALK (IC_{50} = 3 nM) and tropomyosin receptor kinases (TRKs), TRKB (IC_{50} = 54 nM), TRKC (IC_{50} = 193 nM) and TRKA (IC_{50} = 258 nM).

In vitro, zidesamtinib inhibited the viability of cultured cells expressing *ROS1* fusion genes and resistance mutations (G2032R, S1986F, F2004C/V, L2026M, D2033N, and G2101A). In mice subcutaneously implanted with tumors harboring *ROS1* fusions, including the G2032R mutation, administration of zidesamtinib resulted in tumor growth inhibition. Zidesamtinib had antitumor activity in an intracranial NSCLC xenograft model harboring a *ROS1* fusion.

12.2 Pharmacodynamics

Exposure-Response Relationships

An increased incidence of dysgeusia was observed with higher metabolite M9 exposure.

Cardiac Electrophysiology

The largest mean increase in QTc interval was 13 ms (upper confidence interval = 19 ms) after administration of JIDEYTRO 100 mg once daily (the maximum recommended dosage) in patients with advanced ROS1-positive NSCLC and other advanced ROS1-positive solid tumors *[see Warnings and Precautions (5.2)]*.

12.3 Pharmacokinetics

Zidesamtinib pharmacokinetics were observed at steady-state in patients with advanced ROS1-positive NSCLC and other solid tumors at the approved recommended dosage and are presented as mean (coefficient of variation [CV]%) unless otherwise specified. Zidesamtinib maximum plasma concentration (C_{max}) is 934 ng/mL (44%) and total systemic exposure (AUC) is 8,310 ng.h/mL (37%). Zidesamtinib C_{max} and AUC increase in a dose proportional manner over the dose range of 25 mg to 100 mg orally once daily (0.25 to 1 times the maximum recommended dosage). Zidesamtinib accumulation is approximately 1.5-fold and steady-state is reached in approximately 4 days.

Absorption

Zidesamtinib median (min, max) time to maximum plasma concentration (T_{max}) is 1 hour (0.3, 6 hours). Zidesamtinib absolute bioavailability is 83%.

Effect of Food

No clinically significant differences in zidesamtinib exposure were observed in healthy participants following administration of a high fat meal (approximately 1,000 calories with 60% fat).

Distribution

Zidesamtinib apparent (oral) volume of distribution (V_{ss}) is 326 L (18%).

Zidesamtinib plasma protein binding is 79% and is not concentration-dependent in vitro. Zidesamtinib blood-to-plasma ratio was 0.9 in vitro.

Elimination

Zidesamtinib elimination half-life is 18 (51%) hours with an apparent (oral) clearance of 12 (37%) L/h.

Metabolism

Zidesamtinib is primarily metabolized by CYP3A with minor contributions from CYP1A2 and CYP2C8. An active metabolite, a des-ethyl metabolite (M9), with activity one-third that of the parent, was identified in plasma and its AUC represents 48% of the parent AUC.

Excretion

Following oral administration of a single 100 mg radiolabeled dose to healthy participants, approximately 47% of the dose was recovered in the urine (< 1% unchanged) and 33% in the feces (< 2% as unchanged).

Specific Populations

No clinically meaningful differences in the pharmacokinetics of zidesamtinib were observed based on age (26 to 87 years), sex, race (White 44%, Asian 38%, or Black 4%), body weight (36 to 162 kg), eGFR 30 to 90 mL/min [estimated by Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI)], or mild (total bilirubin >1 to 1.5 times ULN or AST > ULN) to moderate (total bilirubin >1.5 to 3 times ULN with any AST) hepatic impairment. The effect of severe (total bilirubin >3 x ULN with any AST) hepatic impairment, severe renal impairment (eGFR < 30 mL/min), or dialysis on zidesamtinib pharmacokinetics is unknown.

Drug Interaction Studies

Clinical Studies

Strong CYP3A Inhibitors: Zidesamtinib AUC increased 2.6-fold and C_{max} increased 1.8-fold following concomitant use of itraconazole (strong CYP3A inhibitor) 200 mg twice daily followed by 200 mg once daily for 6 days.

CYP3A Substrates: No clinically significant differences on midazolam (a sensitive CYP3A substrate) pharmacokinetics were observed when used concomitantly with JIDEYTRO.

Acid-Reducing Agents: No clinically significant difference in steady-state zidesamtinib pharmacokinetics were observed when used concomitantly with lansoprazole (proton pump inhibitor).

In Vitro Studies

CYP450 Enzymes: Zidesamtinib and M9 do not inhibit CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19 or CYP2D6.

UDP-glucuronosyltransferase (UGT): Zidesamtinib does not inhibit UGT1A1, UGT1A3, UGT1A4, UGT1A6, UGT1A9, UGT2B7 or UGT2B15.

Transporter Systems: Zidesamtinib inhibits P-glycoprotein (P-gp), BCRP, and MATE1. Zidesamtinib does not inhibit OATP1B1, OATP1B3, OAT1, OAT3, OCT1, OCT2 or MATE2K.

M9 does not inhibit P-gp, BCRP, MATE1, OATP1B1, OATP1B3, OAT1, OAT3, OCT1, OCT2 or MATE2K.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Carcinogenicity studies with zidesamtinib were not conducted.

Mutagenesis

Zidesamtinib was genotoxic in the in vivo rat micronucleus assays. Zidesamtinib was not mutagenic in the in vitro bacterial reverse mutation (Ames) assay or clastogenic in an in vitro assay in human lymphoblastoid TK6 cells.

Zidesamtinib did not induce DNA strand breaks in the comet assay in liver.

Impairment of Fertility

Dedicated fertility studies were not conducted with zidesamtinib. In a 13-week repeat dose toxicity study with oral administration of zidesamtinib in rats, adverse effects in reproductive organs included hemorrhage and inflammation of the ovaries with dilation and inflammation of the oviduct in females at doses ≥3 mg/kg/day (≥1.7 times the human exposure at the recommended dose based on AUC) and spermatid retention and tubular degeneration in the testis in males at doses ≥6 mg/kg/day (approximately equivalent to the human exposure at the recommended dose based on AUC). Findings in males were reversible, whereas the reversibility in females was not assessed.

14 CLINICAL STUDIES

14.1 Locally Advanced or Metastatic ROS1-Positive NSCLC

The efficacy of JIDEYTRO was evaluated in 117 patients with previously treated locally advanced or metastatic ROS1-positive NSCLC who received JIDEYTRO at a dose of 100 mg orally once daily in ARROS-1, a multicenter, single-arm, open-label, multi-cohort clinical trial (NCT05118789). Eligible patients were required to have ROS1-positive locally advanced or metastatic NSCLC, ECOG performance status ≤1, and measurable disease per RECIST v1.1. Patients with asymptomatic, stable intracranial metastases were eligible. Identification of *ROS1* gene fusions was determined in local laboratories using next-generation sequencing (NGS), polymerase chain reaction (PCR) or fluorescence in situ hybridization (FISH) tests.

The major efficacy outcome measures were confirmed overall response rate (ORR) and duration of response (DOR) according to RECIST v1.1 as assessed by blinded independent central review (BICR). Intracranial response according to modified RECIST v1.1 was assessed by BICR. Tumor assessments with imaging were performed every 8 weeks for the first 18 months and every 12 weeks thereafter. The efficacy population included 117 patients who received at least 1 prior ROS1 TKI with or without prior platinum-based chemotherapy or immunotherapy.

Among the 117 patients with ROS1 TKI-pretreated NSCLC, the median age was 57 years (range 31 to 83); 56% were female; 47% were White; 36% were Asian; 4% were Black or African American and 13% were unknown or other races; 68% never smoked; and 62% had ECOG performance status of 1 at baseline. At baseline, 100% had metastatic disease; 49% had CNS metastases by BICR; 97% had adenocarcinoma; 52% patients had received prior platinum-based chemotherapy for advanced disease; 50% received 1 prior ROS1 TKI (including crizotinib [47%], entrectinib [46%] and repotrectinib and/or taletrectinib [7%]), and 50% received 2 or more prior ROS1 TKIs (including lorlatinib, repotrectinib and/or taletrectinib [93%]).

Efficacy results are summarized in Table 5.

Table 5: Efficacy Results for Patients with ROS1-Positive TKI-Pretreated NSCLC in ARROS-1 per BICR Assessment

Efficacy Parameters	**ROS1 TKI-Pretreated (N=117)**
Confirmed Response Rate, % (95% CI)	44% (34, 53)
Complete Response	0.9%
Duration of Response (DOR)	
Range (months)	1.9, 28.5+
Response Duration ≥6 months [a]	82%
Response Duration ≥12 months [a]	69%

Abbreviations: CI= confidence interval; NE= not evaluable

a Based on observed DOR rate

\+ Ongoing response

In patients who received one prior ROS1 TKI (N=59), the overall response rate was 49% (95% CI: 36, 63). In patients who received two or more prior ROS1 TKIs (N=58), including lorlatinib, repotrectinib and/or taletrectinib, the overall response rate was 38% (95% CI: 26, 52).

Fifty patients had measurable CNS metastases at baseline as assessed by BICR and had not received radiation therapy to the brain within 2 months prior to study entry; responses were observed in 48% (95% CI: 34, 63) of patients including 22% of patients with a complete response.

Responses were observed in 21 of the 42 (50%) patients who had ROS1 resistance mutations. Of the 26 patients with the solvent front G2032R resistance mutation, responses were observed in 14 patients (54%). Responses were also observed in patients with other mutations (ROS1G2032K, ROS1D2033N, ROS1F2004C/V, ROS1G1957A).

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

JIDEYTRO (zidesamtinib) is supplied as follows:

Tablet Strength	Package Configuration	Description	NDC
25 mg	Bottle of 30 tablets packaged in a carton	Pink oblong film-coated tablet, with “25” debossed on one side and “ZDS” on the other side	85001-101-01
100 mg	Bottle of 30 tablets packaged in a carton	Yellow oblong film-coated tablet, with “100” debossed on one side and “ZDS” on the other side	85001-102-01

Storage and Handling

Store JIDEYTRO at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) *[See USP Controlled Room Temperature]*.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Central Nervous System Adverse Reactions

Advise patients of the risk of central nervous system (CNS) adverse reactions during treatment with JIDEYTRO and to inform their healthcare provider if they experience new or worsening CNS symptoms. Advise patients to avoid engaging in hazardous tasks that require mental alertness and motor coordination such as operating machinery or driving a motor vehicle if they are experiencing CNS reactions *[see Warnings and Precautions (5.1)]*.

QTc Prolongation

Advise patients of the risks of QTc interval prolongation during treatment with JIDEYTRO. Advise patients to contact their healthcare provider immediately to report signs or symptoms of arrhythmias *[see Warnings and Precautions (5.2)]*.

Interstitial Lung Disease/Pneumonitis

Advise patients of the risks of ILD/pneumonitis during treatment with JIDEYTRO. Advise patients to inform their healthcare provider if they experience new or worsening pulmonary symptoms indicative of ILD/pneumonitis *[see Warnings and Precautions (5.3)]*.

Skeletal Fractures

Advise patients that bone fractures have occurred in patients taking JIDEYTRO and to report signs or symptoms of fracture to their healthcare provider *[see Warnings and Precautions (5.4)]*.

Myalgia with Creatine Phosphokinase Elevation

Advise patients that JIDEYTRO can cause creatine phosphokinase (CPK) elevations. Advise patients to inform their healthcare provider if they experience muscle pain *[see Warnings and Precautions (5.5)]*.

Pancreatic Toxicity

Advise patients that JIDEYTRO can cause pancreatic toxicity and to contact their healthcare provider if they experience abdominal pain or other symptoms suggestive of pancreatitis *[see Warnings and Precautions (5.6)]*.

Embryo-Fetal Toxicity

- Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females to inform their healthcare provider of a known or suspected pregnancy *[see Warnings and Precautions (5.7), Use in Specific Populations (8.1, 8.3)]*.
- Advise females of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 6 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.
- Advise male patients with female partners of reproductive potential to use effective contraception during treatment with JIDEYTRO and for 3 months after the last dose *[see Use in Specific Populations (8.3)]*.

Lactation

Advise females not to breastfeed during treatment with JIDEYTRO and for 1 week after the last dose *[see Use in Specific Populations (8.2)]*.

Infertility

Advise males and females of reproductive potential that JIDEYTRO may impair fertility *[see Use in Specific Populations (8.3) and Nonclinical Toxicology (13.1)*].

Drug Interactions

Advise patients to inform their healthcare providers of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, and herbal products *[see Drug Interactions (7)]*.

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07/2026

PATIENT INFORMATION
JIDEYTRO™ (jih-DAY-troh)
(zidesamtinib)
tablets

What is JIDEYTRO?

JIDEYTRO is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that:

- has spread within the chest or other parts of the body and is caused by an abnormal ROS1 gene and,
- who have received a ROS1 kinase inhibitor.

It is not known if JIDEYTRO is safe and effective in children.

Before taking JIDEYTRO, tell your healthcare provider about all your medical conditions, including if you:

- have nervous system (neurological) or psychiatric problems.
- have heart problems, including a condition called long QT syndrome.
- have lung or breathing problems other than lung cancer.
- are pregnant or plan to become pregnant. JIDEYTRO can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with JIDEYTRO.
  Females who are able to become pregnant:
  - Your healthcare provider will do a pregnancy test before you start treatment with JIDEYTRO.
  - Use effective birth control (contraception) during treatment and for 6 months after the last dose of JIDEYTRO.
  - Talk to your healthcare provider about birth control methods that may be right for you.

  Males with female partners who are able to become pregnant:
  - Use effective birth control during treatment and for 3 months after the last dose of JIDEYTRO.
- are breastfeeding or plan to breastfeed. It is not known if JIDEYTRO passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of JIDEYTRO. Talk to your healthcare provider about the best way to feed your baby during treatment with JIDEYTRO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking JIDEYTRO with certain other medicines may affect the amount of JIDEYTRO or other medicines in your blood and may cause side effects or affect the way that JIDEYTRO or other medicines work.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take JIDEYTRO?

- Take JIDEYTRO exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking JIDEYTRO unless your healthcare provider tells you to.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with JIDEYTRO if you develop side effects.
- Take JIDEYTRO at about the same time each day with or without food.
- Swallow JIDEYTRO tablets whole. Do not split, chew, crush, or dissolve the tablets. Do not take a tablet if it is broken, cracked, or damaged.
- If you miss a dose of JIDEYTRO take it as soon as possible. If it has been 12 or more hours since you took your last dose, just skip the dose and take it at your next regularly scheduled time.
- If you vomit at any time after taking JIDEYTRO, do not take another dose. Wait to take your next dose at your regularly scheduled time.

What should I avoid while taking JIDEYTRO?

Do not drive or operate heavy machinery during treatment if you develop side effects that can impact your mental alertness or coordination. See “Central nervous system (CNS) effects” in the “What are the possible side effects of JIDEYTRO?” section below.

What are the possible side effects of JIDEYTRO?

JIDEYTRO can cause serious side effects, including:

- **Central nervous system (CNS) effects.** Tell your healthcare provider right away if you, or your family member taking JIDEYTRO, develop any new or worsening CNS symptoms during treatment, including:
  - dizziness
  - fainting
  - walking, balance, or coordination problems
  - forgetfulness, confusion, attention or thinking problems
  - speaking problems
  - seizures
  - mood or personality changes including anxiety, irritability
  - depression, including thoughts of suicide or dying
  - seeing or hearing things that are not real (hallucinations)

- **Changes in the electrical activity of your heart called QT prolongation.** QT prolongation can cause irregular heartbeats that can be life-threatening or cause sudden death. Your healthcare provider will do tests before and during your treatment with JIDEYTRO to check the electrical activity of your heart and your body salts (electrolytes). Tell your healthcare provider right away if you feel faint, lightheaded, dizzy, or feel your heart beating irregularly or fast during your treatment with JIDEYTRO.
- **Lung problems.** JIDEYTRO can cause lung problems that are severe or life-threatening. Tell your healthcare provider right away if you get any new or worsening symptoms of lung problems including trouble breathing, shortness of breath, cough (with or without mucus), or fever.
- **Bone fractures.** JIDEYTRO can increase your risk of bone fractures. Bone fractures may happen with or without a fall or other injury. Tell your healthcare provider if you develop pain, changes in movement, or bone abnormalities.
- **Muscle pain, tenderness, and weakness (myalgia**). JIDEYTRO can cause myalgia with an increase in the level of an enzyme in your blood called creatine phosphokinase (CPK), which may be a sign of muscle damage. Your healthcare provider will do blood tests to check your CPK blood levels every 2 weeks during the first month then every 1 to 2 months and as needed if you get unexplained muscle pain, tenderness, or weakness during your treatment with JIDEYTRO. Tell your healthcare provider if you develop any of these symptoms.
- **Inflammation of the pancreas (pancreatitis).** JIDEYTRO may increase enzymes in your blood called amylase and lipase, which may be a sign of pancreatitis. Your healthcare provider will do blood tests to check your pancreatic enzyme blood levels during treatment with JIDEYTRO. Tell your healthcare provider right away if you get any signs and symptoms of pancreatitis, including upper stomach (abdominal) pain that may spread to the back and get worse with eating, weight loss, or nausea.

The most common side effects of JIDEYTRO include:

- swelling (edema)
- numbness or tingling in your arms or legs
- constipation
- tiredness
- shortness of breath

The most common severe abnormal blood test results include: increased creatine phosphokinase (CPK), increased triglycerides, decreased white blood cell counts and decreased red blood cell counts.

JIDEYTRO may cause fertility problems in males and females. Talk to your healthcare provider if fertility is a concern for you.

These are not all the possible side effects of JIDEYTRO.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store JIDEYTRO?

Store JIDEYTRO at room temperature between 68 °F to 77 °F (20 °C to 25 °C).
Keep JIDEYTRO and all medicines out of the reach of children.

General information about the safe and effective use of JIDEYTRO.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use JIDEYTRO for a condition for which it was not prescribed. Do not give JIDEYTRO to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about JIDEYTRO that is written for health professionals.

What are the ingredients in JIDEYTRO?
Active ingredient: zidesamtinib
Inactive ingredients: The tablet core contains hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, and sodium starch glycolate. The film coating contains hypromellose, titanium dioxide, triacetin, and yellow iron oxide. The 25 mg tablet film coating also contains red iron oxide.

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For more information, go to **www.JIDEYTRO.com** or call 1-844-688-5111.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued July/2026 ZID-US-0097 v1.0