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JideytroTM
(zidesamtinib) | 25 mg
100 mg tablets

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Creating a PowerPlan, Patient List, and ePrescribing Favorites Folder for JIDEYTROTM

Instructions for the Oracle[®] electronic health record (EHR) system

**Please see JIDEYTRO Important Safety Information
on pages 2–5 and [Full Prescribing Information](#).**

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INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION

JIDEYTRO™ (zidesamtinib) 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.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS:

Warnings and Precautions reflect the pooled safety population (N=446) who received JIDEYTRO at a dose of 100 mg orally once daily until disease progression or unacceptable toxicity in ARROS-1.

Central Nervous System (CNS) Adverse Reactions (AR):

- Dizziness, ataxia, cognitive and psychiatric disorders occurred in 25% of patients; 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; of these, 0.2% were Grade 3. Dosage interruption for dizziness was required in 0.4% and dose reduction in 0.7% of patients.
- Ataxia, including gait disturbance and balance disorder, occurred in 2% of patients; all were Grade 1 or 2.
- Cognitive impairment occurred in 9% of patients; 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%), and slow speech (0.2%). Dose interruption for cognitive impairment was required in 1.3% of patients.
- Psychiatric disorders occurred in 6% of patients; 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%). Dosage interruption for psychiatric disorders was required in 0.9% of patients.
- 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.

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IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D):

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.
- 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. QTc prolongation led to dose interruption in 0.4% of patients.
- 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.

Interstitial Lung Disease (ILD)/Pneumonitis:

- JIDEYTRO can cause severe or life-threatening ILD or pneumonitis.
- ILD/pneumonitis occurred in 1.8% of patients, including Grade 3 or 4 in 0.4%.
- ILD/pneumonitis led to dose interruption in 0.7%, dose reduction in 0.2%, and permanent discontinuation 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.

Skeletal Fractures:

- JIDEYTRO can increase the risk of skeletal fractures.
- Five patients (1.1%) experienced skeletal fractures. Grade 3 ankle fractures occurred in two patients (0.4%). Dose interruptions for fractures occurred in 0.4% of patients.
- Promptly evaluate patients with signs or symptoms of fractures.

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WARNINGS AND PRECAUTIONS (CONT'D):

Myalgia with Creatine Phosphokinase (CPK) Elevation:

- JIDEYTRO can cause myalgia with creatine phosphokinase (CPK) elevation.
- Myalgia occurred in 13% of patients. Based on laboratory values, concurrent myalgia with increased CPK occurred in 2.1% of patients.
- 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 JIDEYTRO at the same or reduced dose, or permanently discontinue JIDEYTRO based on severity.

Pancreatic Toxicity:

- JIDEYTRO can cause pancreatic toxicity. In the pooled safety population, among the subgroup of patients who underwent pancreatic lab testing, increased amylase and lipase levels occurred in 22%, and 25% respectively, with Grade 3 increased lipase in 8% of patients. Grade 3 lipase elevation resulted in JIDEYTRO dose reduction in one patient. In the pooled safety population, Grade 3 pancreatitis occurred in one patient (0.2%).
- 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.

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.
- 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.

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).

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ADVERSE REACTIONS:

- The most common adverse reactions ($\geq 15\%$) were edema, peripheral neuropathy, constipation, fatigue, and dyspnea.
- The most common Grade 3 or 4 laboratory abnormalities ($\geq 2\%$) were increased lipase, increased CPK, increased triglycerides, decreased lymphocytes, and decreased hemoglobin.
- 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.

DRUG INTERACTIONS:

Strong and Moderate CYP3A Inhibitors:

- Avoid concomitant use of JIDEYTRO with a strong or moderate CYP3A inhibitor as this could increase JIDEYTRO exposure, 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 as this could decrease JIDEYTRO exposure, which may decrease the effectiveness of JIDEYTRO.

Please see [Full Prescribing Information](#).



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Overview and Limitations

- This document provides healthcare organizations with instructions for creating or updating a PowerPlan, creating a patient list, and adding JIDEYTRO to the ePrescribing Favorites Folder in the Oracle Health EHR system 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.
- The document is informational only. It does not replace professional medical advice, diagnosis, or clinical judgment. Treatment selection is always a decision made by the healthcare provider.
- The processes and instructions outlined in this document may not be complete or accurate for your organization. Additionally, some steps are variable, and not all steps will apply to every organization. Any steps or settings that are not part of an organization's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider.
- These instructions are specific to JIDEYTRO and the Oracle Health EHR system and are not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.
- The organization is solely responsible for the implementation, testing, monitoring, and ongoing operation of any EHR tools.



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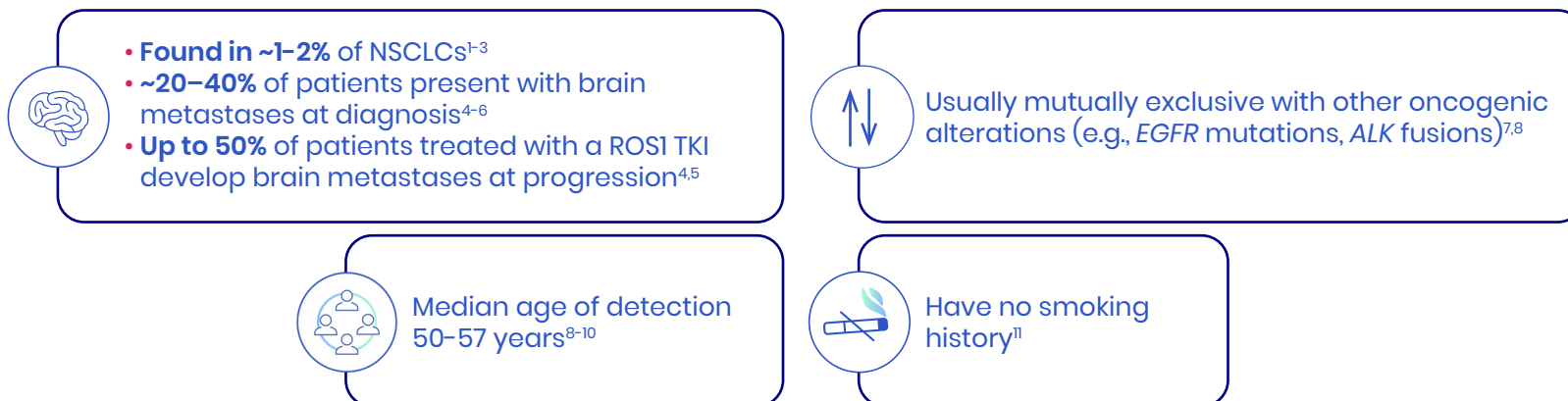
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Locally Advanced or Metastatic *ROS1*-Positive Non-Small Cell Lung Cancer Medical Needs

Patients With Advanced *ROS1*+ NSCLC Represent a Rare and Clinically Distinct Subset of Advanced NSCLC

Common characteristics for patients with *ROS1* fusions:



Detection of *ROS1* fusions^{2,12}

ALK, anaplastic lymphoma kinase; *EGFR*, epidermal growth factor receptor; FISH, fluorescence in situ hybridization; NSCLC, non-small cell lung cancer; NGS, next-generation sequencing; PCR, polymerase chain reaction; *ROS1*, c-ros oncogene 1; TKI, tyrosine kinase inhibitor.



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Locally Advanced or Metastatic *ROS1*-Positive Non-Small Cell Lung Cancer Medical Needs

Significant Medical Needs Remain for Patients With *ROS1*+ NSCLC^{13,14}



***CNS activity*^{5,13,15}**

Suboptimal intracranial inhibition may limit activity against brain metastases, a key driver of disease progression



***ROS1 selectivity*¹⁴**

Inadequate target selectivity may lead to off-target or dose-limiting toxicities, treatment intolerance, and increased patient burden



***ROS1 mutant activity*^{13,14}**

ROS1 resistance mutations acquired during treatment with targeted therapies may lead to disease progression

These drivers of disease progression or intolerance may lead to early treatment discontinuation, highlighting the need for a durable treatment option.¹³⁻¹⁵

CNS, central nervous system; NSCLC, non-small cell lung cancer; *ROS1*, c-ros oncogene 1.



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Locally Advanced or Metastatic *ROS1*-Positive Non-Small Cell Lung Cancer Medical Needs and JIDEYTRO

JIDEYTRO: A Rationally Designed, *ROS1*-Selective TKI



Indicated for the treatment of adult patients with locally advanced or metastatic *ROS1*+ NSCLC who received a prior *ROS1* kinase inhibitor¹⁶

SCIENTIFIC RATIONALE for JIDEYTRO

ROS1 Activity

- Primary oncogenic driver in ~1–2% of NSCLC¹⁻³

ROS1 Mutant Activity

- ~40% of patients develop secondary *ROS1* G2032R resistance mutations following crizotinib treatment¹⁷

Intracranial Activity

- ~20–40% of patients present with CNS metastases at diagnosis^{4,5}
- ~30–55% of patients develop CNS metastases following 1L crizotinib^{4,17}



1L, first line; CNS, central nervous system; NSCLC, non-small cell lung cancer; *ROS1*, c-ros oncogene 1; TKI, tyrosine kinase inhibitor.

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).

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PowerPlan Considerations

The clinical data elements provided in this section for PowerPlans are suggestions only. Clinical and operational leadership must determine that the final elements align with the expectations and goals of the organization, as well as all applicable policies, standards, and laws and regulations. Consider reviewing appropriate PowerPlans for the inclusion of JIDEYTRO. PowerPlans may benefit from regular updates to include new treatments, laboratory sets, and other orderable items.

The content in this section provides an overview and quick reference guide for the dosing and administration details for JIDEYTRO as per the Prescribing Information. Step-by-step instructions for applying these medication details in PowerPlan updates are shown in the instructions section for your consideration.

However, treatment selection is always a decision made by the healthcare provider, and PowerPlans may be overridden to reflect this. An EHR newsletter or other communication may be considered to notify end users of the availability and contents of the updated PowerPlans.

Suggested PowerPlan Content

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.

Key clinical details from the JIDEYTRO Prescribing Information are included in this section and may be incorporated as part of creating/updating the PowerPlan based on the suggested steps in the instructions section that follows. JIDEYTRO should be used only as described in the Prescribing Information. The organization may add or edit any details as desired to align with governing EHR policies and standards.

Please consult the most recent version of the JIDEYTRO Prescribing Information for full treatment details.

Please see JIDEYTRO Important Safety Information on pages 2–5 and Full Prescribing Information.

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PowerPlan Considerations (cont'd)

The following content is from the JIDEYTRO Prescribing Information:

Recommended Testing and Evaluation Before Initiating JIDEYTRO

Before initiating JIDEYTRO, evaluate creatine phosphokinase (CPK) level, electrocardiogram (ECG), electrolytes, lipase, and amylase.

Recommended Dosage

The recommended dosage of JIDEYTRO is 100 mg taken orally once daily, with or without food, until disease progression or unacceptable toxicity. 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.

Dosage Modifications 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.	

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).





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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	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	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.
	Grade 3 (QTc interval ≥ 501 msec or QTc)	- Withhold JIDEYTRO until recovery to Grade ≤ 1 or baseline. - Correct electrolytes and/or change concomitant medications. - Resume JIDEYTRO at a reduced dose.

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

Table continued on next page

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).





PowerPlan Considerations (cont'd)

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

Table 2 (cont'd): Recommended Dosage Modifications of JIDEYTRO for Adverse Reactions

Adverse Reaction	Severity*	Dosage Modification
QTc Interval Prolongation	Grade 4 (Torsade de pointes; polymorphic ventricular tachycardia; signs/symptoms of serious arrhythmia)	• Permanently discontinue JIDEYTRO.
Interstitial Lung Disease (ILD)/Pneumonitis	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.

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

Table continued on next page

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PowerPlan Considerations (cont'd)

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

Table 2 (cont'd): Recommended Dosage Modifications of JIDEYTRO for Adverse Reactions		
Adverse Reaction	Severity*	Dosage Modification
Interstitial Lung Disease (ILD)/Pneumonitis	Grade 3 or 4	Permanently discontinue JIDEYTRO.
	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.
	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.
Increased lipase or amylase	Grade 4	Permanently discontinue JIDEYTRO.

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

Table continued on next page

Please see JIDEYTRO Important Safety Information on pages 2–5 and [Full Prescribing Information](#).





PowerPlan Considerations (cont'd)

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

Table 2 (cont'd): Recommended Dosage Modifications of JIDEYTRO for Adverse Reactions

Adverse Reaction	Severity*	Dosage Modification
Pancreatitis	Grade 3 or 4	• Permanently discontinue JIDEYTRO.
Other Adverse Reactions	Intolerable Grade 2 or Grade 3 or Grade 4	• Withhold JIDEYTRO until Grade $\leq$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. • Permanently discontinue JIDEYTRO for recurrent Grade 4 events.

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

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Contraindications

None.

Central Nervous System Adverse Reactions

JIDEYTRO can cause central nervous system adverse reactions.

In the pooled safety population, 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.

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Central Nervous System Adverse Reactions (cont'd)

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.

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, 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.

Interstitial Lung Disease/Pneumonitis

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

In the pooled safety population, 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).

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PowerPlan Considerations (cont'd)

Interstitial Lung Disease/Pneumonitis (cont'd)

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.

Skeletal Fractures

JIDEYTRO can increase the risk of skeletal fractures. In the pooled safety population, 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.

Myalgia with Creatine Phosphokinase Elevation

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

In the pooled safety population, 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.

Pancreatic Toxicity

JIDEYTRO can cause pancreatic toxicity. In the pooled safety population, among the subgroup of patients who underwent pancreatic lab testing,

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Pancreatic Toxicity (cont'd)

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, 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.

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.



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PowerPlan Instructions

- PowerPlans are commonly used in the management of oncology patients. PowerPlans consolidate notes, referrals, imaging studies, lab orders and bundles, medications, patient education, coding and billing information, and other orderable items used to manage a medical condition, problem, or age-specific need. PowerPlans may improve the user experience and help reduce practice variation. They are typically created and modified at the enterprise or system level to help reduce practice- or location-specific variation.
- PowerPlans may benefit from clinical updates to incorporate treatment changes or system optimizations. Typically, a practice will conduct a clinical review process to review and approve suggested optimizations. Various stakeholders may participate in reviewing optimization requests prior to implementation. Engage the proper committees and stakeholders for clinical input and review well ahead of the planned implementation date.
- Any updates to the content or availability of PowerPlans should be communicated to end users, with training provided as needed. In many cases, end users will have already been trained on how to use these tools as part of the organization's best practices, thereby potentially reducing the need for additional training.
- PowerPlans may be used to set up JIDEYTRO in the Oracle Health EHR system. Administrative user rights are required to access these tools. An existing PowerPlan may be used as the foundation for a new one. Consider modifying an existing PowerPlan as a starting template while saving the original. PowerPlans and related content will need to be built by a clinical analyst, an IT colleague, or other qualified professional, or as otherwise determined by the organization.

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PowerPlan Instructions (cont'd)

There are 3 main steps to creating or updating a PowerPlan in the Oracle Health EHR system to include JIDEYTRO:

1

Establish the PowerPlan.

Option 1: Find an existing PowerPlan to modify

Option 2: Create a new PowerPlan

2

Modify the PowerPlan to include JIDEYTRO.

3

Add links to the JIDEYTRO Prescribing Information and other resources to the medication record.



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Step 1: Establish the PowerPlan

Option 1 – Find an Existing PowerPlan to Modify

1. **Open DCP tools** (dcptools.exe).
2. **Select the PowerPlan Tool** in the Order Management section.
3. **Click Task > Open Plan** or click the folder icon to search for an existing PowerPlan.
4. Search for and select an existing PowerPlan that may serve as a template to optimize. Double-click the plan to display its contents.
Note: The existing PowerPlan will only serve as a template for the new JIDEYTRO™ PowerPlan. When looking for existing PowerPlans, consider searching for:
 - i. ONC, ONCP, LUNG, NSCLC, ROS1, ROS1-POSITIVE
5. While on the PowerPlan level, name the PowerPlan by updating the Display Description in the Attribute pane. Consider the following name or follow your organization's naming conventions:
 - i. JIDEYTRO™ (zidesamtinib) for adult patients with TKI-pretreated, advanced ROS1-positive NSCLC
6. **Click Save** to create a new version of the PowerPlan that can now be modified.

Option 2 – Create a New PowerPlan

1. **Open DCP tools** (dcptools.exe).
2. **Select the PowerPlan Tool** in the Order Management section.
3. **Click Tasks > New Plan** or click the Create New Plan icon.
4. **Enter a name for the PowerPlan.** Consider the following name or follow your organization's naming conventions:
 - i. JIDEYTRO™ (zidesamtinib) for adult patients with TKI-pretreated, advanced ROS1-positive NSCLC
5. **Select Single Phase or Multiple Phase** based on your organization's practice setting.
Note: Single phase plans are typically used in acute settings, while multiple phase plans are used in surgical settings. If Multiple Phase is selected, add the phases by typing in a name for each phase in the Add New Phase section and clicking Add.
6. **Select the Plan Type** (e.g., Medical, Oncology, Infusion) based on your organization's build standards for oral oncology therapy.
7. **Set the Display Method** as Clinical Category.

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Step 2: Modify the PowerPlan to include JIDEYTRO™

1. While on the PowerPlan level, select the row for Reference Text in the Attribute pane and enter the following text:
 - i. JIDEYTRO™ is 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.
2. **Click OK.**
3. **Select the Prescription tab** in the lower right-hand panel and enter “JIDEYTRO™ (zidesamtinib)” in the Start Search At field. Select the JIDEYTRO™ order from the results, click the right arrow to move it into the Current list, and click Add.

Note: Ensure the appropriate Clinical Category is selected for the order before clicking Add.
4. **Click the checkbox** next to Include to include the prescription in the plan by default.
5. **Scroll to the bottom** of the Attribute pane for the JIDEYTRO™ prescription and right-click the Order Sentence row to enter order details such as dose, route, frequency, and any free-form special instructions for nurses, pharmacists, or healthcare professionals (HCPs). Consider the following clinical details from the Prescribing Information:
 - i. 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 other side of the tablet. JIDEYTRO tablets, 100 mg are film-coated, oblong, yellow tablets, debossed with “100” on one side and “ZDS” on other side of the tablet.
 - ii. 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).
 - iii. Before initiating JIDEYTRO, evaluate creatine phosphokinase (CPK) level, electrocardiogram (ECG), electrolytes, lipase and amylase.
 - iv. Recommended Dosage:
 1. The recommended dosage of JIDEYTRO is 100 mg taken orally once daily, with or without food, until disease progression or unacceptable toxicity. Swallow JIDEYTRO tablets whole. Do not split, chew, crush, or dissolve the tablet prior to swallowing.
 2. 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.

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Step 2: Modify the PowerPlan to include JIDEYTRO™ (cont'd)

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

v. Contraindications

None.

vi. Warnings and Precautions

Warnings and Precautions include central nervous system adverse reactions, QTc interval prolongation, interstitial lung disease (ILD)/pneumonitis, skeletal fractures, myalgia with creatine phosphokinase elevation, pancreatic toxicity, and embryo-fetal toxicity. For warning and precaution details, see Section 5 of the JIDEYTRO Prescribing Information.

6. **Select the Order tab** in the lower right-hand panel and search for your organization's scheduling or follow-up orders in the Start Search At field, as applicable. Select the desired orders from the results, click the right arrow to move them into the Current list, and click Add.

Note: Ensure the appropriate Clinical Category is selected for the orders before clicking Add.

7. **Click the Treatment Schedule section** to update the treatment schedule.

Note: This will be at the PowerPlan level for single phase plans and at the phase level for multiple phase plans.

8. **Next to Enter Length of Treatment Schedule**, enter the desired treatment duration value and unit (e.g., 30 days). Set the Treatment Schedule to start with Day 1. Check off the days for which there will be treatment under Select Treatment Periods. Indicate how long each treatment period will be (12 hours is recommended for outpatient settings).

9. **Click the checkbox for Day 1** on the row for JIDEYTRO™ and click OK. Select the appropriate days for the scheduling orders.

10. **Add any other desired orderable items** and information to the PowerPlan and treatment schedule. This may include information for JIDEYTRO™ treatment conditions, monitoring and hold parameters, warnings and precautions, supportive care, schedulable orders, HCP communications, and other sections as desired.

11. **Click Task > Save Plan.**

12. **Validate the newly optimized PowerPlan.**

13. **Release the plan** to the production environment after completing testing.

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Step 3: Add links to the Prescribing Information and other resources

1. Access the medication database (Multum) using the Order Catalog Tool and find JIDEYTRO™.
2. Select the Reference Text tab.
3. Select the type of reference text from the Text Type list.
4. Select New to create reference text.
5. A new row will appear in the Text Variation pane labeled “New Variation.” Double-click to update the name (e.g., “JIDEYTRO™ Prescribing Information and other resources”). Ensure a red check mark is displayed under the Active column.
6. In the Reference Text section, select the hyperlink icon. A dialogue box will appear.
 - i. For the Linked Text field, enter “JIDEYTRO™ Prescribing Information”
 - ii. For the Link To field, copy and paste the following link: <https://www.jideytrohcp.com/prescribing-information.pdf>
7. Click OK and hit Enter to move the cursor to the next line.
8. Select the hyperlink icon again and repeat steps 6 and 7 until all desired links have been added.
9. Click Apply to save the customized reference text.



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Patient List Considerations

Consider using Oracle Health's Discern Analytics 2 (DA2) reporting tool to create a patient list. Consult your organization if administrative user rights are required to access the reporting solutions. Review documentation practices in the EHR when considering creating the patient report.

Additional reporting solutions are available; however, use of these tools typically requires analyst or reporting privileges and is beyond the scope of most users.

The steps below will assist an end user in creating a patient query (also referred to as a "patient list" or "report") to identify patients with potential care gaps. Consider creating a patient query to identify patients with locally advanced or metastatic *ROS1*-positive NSCLC who have previously received a *ROS1* kinase inhibitor and may be candidates for treatment with JIDEYTRO.

The suggested criteria are listed on the following pages. Not every criterion may be routinely documented in the EHR and, depending on the level of integration within the practice or health system, some criteria may be unavailable. For example, biomarker results may not be available in the EHR as structured data. Given variations in documentation and coding practices, the suggested criteria may need to be modified. Any questions should be directed to the appropriate service provider. The health system is solely responsible for the implementation, testing, monitoring, and ongoing operation of any EHR tools.

A manual chart review of the resulting patient list is recommended, as the list is not a substitute or a replacement for the clinical or professional judgment of the healthcare provider. While EHRs may assist providers in identifying patients who may be appropriate for JIDEYTRO therapy, treatment decisions should ultimately be made by the provider in consultation with the patient following review of the patient's medical records to confirm eligibility.



Suggested Inclusion Criteria

Consider using the clinical criteria below to help generate a list of patients diagnosed with NSCLC who may have advanced *ROS1*+ disease and be eligible for JIDEYTRO therapy.

Demographics:

- Living status: Alive
- Age: ≥ 18 years old

Diagnosis: Lung cancer (C34.xx)¹⁸

C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.20	Malignant neoplasm of middle lobe, unspecified bronchus or lung
C34.21	Malignant neoplasm of middle lobe, right bronchus or lung
C34.22	Malignant neoplasm of middle lobe, left bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

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Suggested Inclusion Criteria (cont'd)

Consider using the clinical criteria below to help generate a list of patients diagnosed with advanced *ROS1*+ NSCLC who may be eligible for JIDEYTRO therapy.

Staging:

Stage III locally advanced, Stage IIIB/C, Stage IV,
OR Locally advanced or metastatic disease (TNM):

- Tumor status: T4b
- Nodal status: N1-3
- Metastatic status: M1

Biomarker (if available):

- *ROS1* positive

Previous Medications:

1. Pharmaceutical class: *ROS1* kinase inhibitor

Note: Depending on how information was documented in the EHR, staging information may not always be available as structured data. Consider running the patient query and confirm the patient's staging information with a manual chart evaluation.

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Instructions:

1. **Launch Discern Analytics 2.0 (DA2.exe).** It may be found as DA2.exe in the applications folder.
2. **Click the Domains tab** to access available domains. Select the oncology domain.
Note: Available domains vary by health system. Check for an oncology domain with oncology disease, staging, and regimen information. If a domain with oncology-specific data is not available, consider reaching out to your organization's data team.
3. **Select File > New > Query** or select the desired oncology domain by double-clicking it. The query wizard will display available categories.
4. In the **Qualifications window**, select the Person > Demographics > Age filter and click Modify Filter List.
5. **Set the age range** to 18 years and older. Click Include.
6. In the Qualifications window, **select Diagnosis Code** (or Oncology Disease) and click Modify Filter List.
7. Enter the **applicable lung cancer diagnosis codes** (C34.xx) and click Include.
8. In the Qualifications window, **select the staging option** (if available) and click Modify Filter List.
9. Enter the **applicable staging information** for locally advanced or metastatic disease and click **include**:
 - i. Stage III
 - ii. Stage IIIB
 - iii. Stage IIIC
 - iv. Stage IV**OR**
 - v. T4b
 - vi. N1-N3
 - vii. M1*Note: Availability of stage and TNM data varies by organization and oncology workflow.*
10. In the Qualifications window, **select the Procedures Filter and click Modify Filter List** if biomarker data are available as structured data.

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Instructions (cont'd):

- 11. Enter the applicable biomarker procedure** for ROS1-positive disease.

Note: ROS1 biomarker results may not be available as structured EHR data and may instead reside in pathology reports, molecular testing reports, scanned documents, or external laboratory systems.

- 12. In the Qualifications window, select the Orders > Order Synonym ID filter** and click Modify Filter List.

- 13. Enter and select ROS1 kinase inhibitor medications** and select Include for all medications.

- 14. Using the Report Logic field**, set the operator logic to:

Age ≥18 years

AND

Lung cancer diagnosis

AND

Locally advanced or metastatic disease

AND

ROS1-positive biomarker status (if available)

AND

Prior ROS1 kinase inhibitor therapy

- 15. Select all the desired columns** to include in the report by selecting the column and then clicking the right arrow to the Selected Columns window. Select and add the current diagnoses and current medications and any other desired displayed columns. Consider the following columns based on availability at your organization:

- i. Oncology Disease
- ii. Cancer Stage
- iii. TNM Staging
- iv. Biomarker Results
- v. PowerPlans
- vi. Current Medications
- vii. Treating Provider
- viii. MRN

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Instructions (cont'd):

- 16. Save the query with a unique name** (e.g., “**Adult Patients With Locally Advanced or Metastatic ROS1-Positive NSCLC Who Received Prior ROS1 Kinase Inhibitor Therapy and May Be Candidates for JIDEYTRO**”)
- 17. Click Query >** Query review or Run Query in Viewer in the Query tab to run and save the query.
- 18. The results will display.** The results may be further manipulated if desired or exported to Excel. Complete a manual chart review of the resulting patient list to confirm diagnosis, stage, biomarker status, treatment history, and overall eligibility.

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ePrescribing Favorites Folder Instructions

Consider making frequently used medication records and PowerPlans favorites to help streamline order entry and improve workflow efficiency. Favorited items are readily accessible within the Favorites folder, reducing the need to repeatedly search for the same records. The instructions below outline how to add the JIDEYTRO medication record and JIDEYTRO PowerPlan to your Favorites folder for easier access during patient care.

Note: Naming conventions may vary by institution. If JIDEYTRO is not found, search using the generic name, formulary name, or other locally configured synonyms used by your organization.

Instructions for saving JIDEYTRO to an ePrescribing Favorites folder

1. Enter JIDEYTRO in the Search field of the Add Order window and press Enter.
2. Select the JIDEYTRO order in the search results.
3. Right-click the order and select Add to Favorites.
4. The Add Favorite window will open. Choose one of the following:
 - i. Save the medication to an existing Favorites folder.
 - ii. Create a new folder by clicking New Folder and entering a folder name.
5. Click OK to add the medication to your Favorites.

Instructions for saving JIDEYTRO to a custom ePrescribing Favorites folder

1. Add the JIDEYTRO medication order and complete the desired order details (dose, route, frequency, etc.).
2. Before signing the order, right-click the medication order.
3. Select Add to Favorites.
4. Save the customized order sentence to the desired Favorites folder.

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ePrescribing Favorites Folder Instructions (cont'd)

Instructions for saving JIDEYTRO as a PowerPlan to an ePrescribing Favorites folder

1. Enter JIDEYTRO in the Search field of the Add Order window and press Enter.
2. Select the JIDEYTRO PowerPlan in the search results.
3. Right-click the PowerPlan in the search results and select Add to Favorites.
4. The Add Favorite window will open. Choose one of the following:
 - i. Save the medication to an existing Favorites folder.
 - ii. Create a new folder by clicking New Folder and entering a folder name.
5. Click OK to add the PowerPlan to your Favorites.

Instructions for saving JIDEYTRO as a PowerPlan to a custom ePrescribing Favorites folder

1. Open the JIDEYTRO PowerPlan and make the desired modifications (order sentence selection, include or remove orders, etc.)
2. Click Save as My Favorite.
3. Enter a unique name to differentiate the customized JIDEYTRO PowerPlan from the original one.
4. Click OK to save the modified JIDEYTRO PowerPlan to your Favorites.

Optional: Instructions to organize your Favorites folders

1. Click the down arrow next to the Favorites button.

Note: New folders and unmodified PowerPlans are saved here. PowerPlans that you modify and save as a favorite are saved in the My Favorite Plans folder.
2. Select Organize Favorites.
3. The Organize Favorites window opens. Use the available options to:
 - i. Add, rename, or delete folders.
 - ii. Rearrange or delete favorites orders.



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Jideytro[™]
(zidesamtinib) | 25 mg
100 mg tablets

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