

INDICATION and IMPORTANT SAFETY INFORMATION

INDICATION

What is JIDEYTRO™ (zidesamtinib)?

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.

IMPORTANT SAFETY INFORMATION

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.

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 a female partner 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.

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.

What are the most common side effects of JIDEYTRO?

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 are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see [Full Prescribing Information](#) and [Patient Information](#) for JIDEYTRO.

Nuvalent is a registered trademark of Nuvalent, Inc., and JIDEYTRO is a trademark of Nuvalent, Inc.

©2026 Nuvalent, Inc. All rights reserved. ZID-US-0213v1.0 07/2026