Zidesamtinib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for non-small cell lung cancer (NSCLC).
- It may also be used for other reasons.
- Your care team may perform a test for a specific type of abnormal ROS1 gene to make sure zidesamtinib is right for you.

Goal of Treatment: _____

- Treatment may continue for a certain time period, until it no longer works, or until side effects are no longer controlled.

Treatment Regimen

Treatment Name	How the Treatment Works	How the Treatment is Given
Zidesamtinib (ZYE-de-SAM-tih-nib): Jideytro (jih-DAY-troh)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive	Tablet(s) taken by mouth.

Treatment Administration and Schedule

Your zidesamtinib dosing instructions:

_____

_____

_____

- Zidesamtinib comes in 2 tablet strengths: 25 mg and 100 mg.
- Your dose might differ, but zidesamtinib is typically taken as one 100 mg tablet by mouth once daily.
- Take zidesamtinib 1 time a day, at about the same time each day with or without food.
- Swallow zidesamtinib tablets whole. Do not split, chew, crush, or dissolve the tablets. Do not take a tablet if it is broken, cracked, or damaged.
- Do not change your dose or stop taking zidesamtinib unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking zidesamtinib if you develop certain side effects.
- If you miss a dose of zidesamtinib 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 zidesamtinib, do not take another dose. Wait to take your next dose at your regularly scheduled time.
- If you take too much zidesamtinib, call your care team or go to the nearest hospital emergency room right away.

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Storage and Handling of Zidesamtinib

- Store zidesamtinib at room temperature between 68ºF and 77ºF (20ºC and 25ºC).
- Keep zidesamtinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused zidesamtinib.

Appointments

Appointments may include regular check-ups with your care team, lab visits, and imaging tests. It's important to keep your appointments whenever you can. If you miss an appointment, call your care team as soon as possible to reschedule it.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
Supportive care used to treat or prevent side effects	

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Common Side Effects

Side Effect	Important Information
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	Description: Red blood cells carry oxygen throughout your body. Low levels can make you feel tired, weak, dizzy, or short of breath. Recommendations: • Aim for 7 to 8 hours of sleep each night. • Do not drive, operate heavy machinery, or do other dangerous activities if you are very tired. • Balance activity and rest — stay as active as you can, but rest when needed. • Eat a balanced diet and follow any nutrition or supplement advice from your care team. Talk to your care team if you have: • Shortness of breath • Dizziness or fainting • Fast or irregular heartbeats • Sudden or severe headache
Swelling (Edema)	Description: Swelling and fluid retention can occur in different areas of the body, like the legs or hands. You might notice areas feel puffy or tighter than usual. Recommendations: • Weigh yourself daily and keep a record to notice sudden weight gain. • Elevate swollen legs when sitting and avoid standing for long periods. • Wear compression stockings if your care team recommends them. • Remove rings if your fingers begin to swell. • Limit salt (sodium) intake and follow any fluid restrictions your care team gives. • Stay active and do gentle movement to improve circulation. Talk to your care team if you have: • Swelling that suddenly worsens or spreads to other areas • Pain, redness, or warmth in the affected area • Shortness of breath or difficulty breathing • Persistent swelling that does not improve with home management • Unexpected weight gain Note: Your care team may ask you to contact them if your weight increases by a certain amount over a certain time period.
High Cholesterol and Triglycerides Levels in Your Blood (Hyperlipidemia)	Description: Treatment can raise cholesterol and triglyceride levels in your blood. While cholesterol is needed by the body, high levels can increase the risk of heart disease. Triglycerides are blood fats, and very high levels can increase your risk of pancreatitis and heart problems. Recommendations: • Choose foods low in saturated and trans fats. • Eat more foods that are high in fiber. • Stay active with regular physical activity. • Try to keep a healthy weight. • Don’t smoke, and limit how much alcohol you drink. Talk to your care team if you have: • Sudden numbness or weakness • Chest pain • Other signs of a heart attack or stroke

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Liver Problems	Description: Treatment can cause liver injury. Your care team may check your liver with blood tests before and during treatment. Talk to your care team if you have: • Yellowing of your skin or the white part of your eyes (jaundice) • Severe nausea or vomiting • Pain on the right side of your stomach area (abdomen) • Dark, tea-colored urine • Bleeding or bruising more easily than normal
Numbness, Tingling, or Burning in Your Hands or Feet (Peripheral Neuropathy)	Description: Nerve pain and tingling are uncomfortable sensations from nerve damage or irritation. Pain may be sharp, burning, or deep. Tingling can feel like pins-and-needles or mild electric shocks, often in the hands, feet, arms, or legs. Recommendations: • Keep a daily log of pain and sensations, noting triggers and what helps or makes it worse. • Check your feet every day for cuts, sores, blisters, or color changes, especially if numbness reduces feeling. • Wear comfortable, well-fitting shoes and avoid walking barefoot if sensation is reduced. • Protect hands and feet from extreme heat or cold. • Your care team may recommend or prescribe medicines, topical treatments, physical therapy, or supplements to help with symptoms. Talk to your care team if you have: • New or worsening “pins and needles”, burning, or numbness in your hands or feet • Trouble moving your arms or legs, or weakness • Problems with balance or frequent falls
Muscle, Bone, or Joint Pain	Description: Muscle pain is soreness, aching, cramps, stiffness, tenderness, or weakness in one or more muscles. Joint pain is pain, stiffness, swelling, or reduced movement where two bones meet. Bone pain is a deep, aching or sharp pain in or around a bone that may worsen with movement or pressure. Zidesamtinib can increase the level of an enzyme in your blood called creatine phosphokinase (CPK), which may be a sign of muscle damage. Recommendations: • Keep a pain diary: note pain levels, locations, and activities that make it better or worse. • Do gentle exercise (walking, stretching, yoga) to maintain mobility and strength. Check with your care team before starting a new activity. • Use a warm compress for stiff muscles or a cold pack to reduce swelling and numb pain—use what helps the area. • Your care team may recommend or prescribe medicines, including over-the-counter pain relievers. Talk to your care team if you have: • Pain you cannot control with usual measures • Swelling, redness, or warmth in a joint • New weakness • Trouble walking or moving

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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Changes in the Electrical Activity of Your Heart Called QT Prolongation	QT prolongation can cause irregular heartbeats that can be life-threatening. • Feel faint, lightheaded, dizzy • Fast or irregular heartbeat
Lung Problems	Zidesamtinib can cause lung problems that may be serious, life-threatening, or fatal. Lung problems can include inflammation or scarring in the lungs called interstitial lung disease (ILD) or pneumonitis. If you develop lung problems, your care team may treat you with corticosteroid medicines. Call your care team right away if you develop: • Cough • Trouble breathing or shortness of breath • Fever • Other new or worsening breathing symptoms such as chest tightness or wheezing
Brain Problems	• Headache • Dizziness • Confusion • Memory problems • Difficulty concentrating • Fatigue • Seizures • Muscle weakness • Tremors • Changes in mood or behavior • Sensory disturbances (such as tingling or numbness)
Bone Fracture	• Sharp pain that worsens with movement • Swelling or bruising around the broken bone • Difficulty moving or bearing weight on the injured area • Limb that looks crooked, bent, or shorter than the other side
High Amylase and Lipase Levels in Your Blood	• Fever of 100.4°F (38°C) or higher • Fast heartbeat • Severe stomach-area (abdominal) pain that radiates to the back • Worsening pain after eating • Severe nausea or vomiting • Diarrhea • Yellowing of your skin or the white part of your eyes (jaundice)

Before starting treatment, ask your care team when to call 9-1-1 or seek emergency help.
If you experience any new, worsening, or uncontrolled side effects, contact your care team immediately.

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Intimacy, Fertility, Pregnancy, and Breastfeeding

- Treatment may **change how you feel about intimacy and your body.** However, physical closeness—such as holding hands and hugging—remains safe. It is common to have questions about intimacy. If needed, talk to your care team for guidance.
- Treatment can affect your **ability to have children**. It may damage your reproductive organs or stop them from working. If you are worried about fertility, talk to your care team before starting treatment.
- Treatment may **harm an unborn baby**.
    - If you are able to become pregnant:
        - Your care team will verify your pregnancy status before treatment.
        - Use an effective method of birth control during treatment and for 6 months after your last dose of zidesamtinib.
        - If you think you might be pregnant or if you become pregnant, tell your care team right away.
    - If your partner is able to become pregnant, use an effective method of birth control—such as condoms—during treatment and for 3 months after your last dose of zidesamtinib.
- **Do not breastfeed** during treatment and for 1 week after your last dose of zidesamtinib.

Additional Information

- **Tell your care team about all the medicines you take**.
  This includes prescriptions, over-the-counter drugs, vitamins, and herbal products. Before starting any new medicine, supplement, or vaccine, ask your care team first.
- **You should not drink grapefruit juice or eat grapefruit during treatment with zidesamtinib**. Grapefruit may increase the amount of zidesamtinib in your blood.
- **Zidesamtinib can make you feel dizzy**. Do not drive or operate machinery until you know how zidesamtinib affects you.
- **This Patient Education Sheet may not describe all possible side effects.**
  Call your care team for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Notes

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