Ivosidenib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for:
  - Acute myeloid leukemia (AML)
  - A type of blood cancer called myelodysplastic syndrome (MDS)
  - A type of bile duct cancer called cholangiocarcinoma (CCA)
- It may also be used for other reasons.
- Your care team will perform a test for a specific type of abnormal gene in isocitrate dehydrogenase-1 (IDH1) to make sure ivosidenib 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
Ivosidenib (I-voh-SIH-deh-nib): Tibsovo (tib-SOH-voh)	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 ivosidenib dosing instructions:

_____

_____

_____

- Ivosidenib comes in 1 tablet strength: 250 mg.
- Your dose might differ, but ivosidenib is typically taken as two 250 mg tablets (500 mg total dose) by mouth once daily.
- Take ivosidenib 1 time a day, around the same time each day.
- Swallow ivosidenib tablets whole. Do not split, crush, or chew the tablet.
- Ivosidenib can be taken with or without food.
- Do not take ivosidenib with a high-fat meal. An example of a high-fat meal includes 2 eggs fried in butter, 2 strips of bacon, 2 slices of white bread with butter, 1 croissant with 1 slice of cheese, and 8 ounces of whole milk (approximately 1,000 calories and 58 grams of fat).

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Treatment Administration and Schedule Continued

- Do not change your dose or stop taking ivosidenib unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking ivosidenib if you develop certain side effects.
- If you vomit after taking a dose of ivosidenib, do not take an additional dose. Take your next dose at your usual time.
- If you miss a dose of ivosidenib or did not take it at the usual time, take your dose as soon as possible and at least 12 hours before your next dose. Return to your normal schedule the following day. Do not take 2 doses of ivosidenib within 12 hours.
- If you take too much ivosidenib, call your care team or go to the nearest hospital emergency room right away.

Storage and Handling of Ivosidenib

- Store ivosidenib at room temperature between 68°F and 77°F (20°C and 25°C).
- Do not remove the desiccant canister from the bottle.
- People who are or may be pregnant should wear gloves when handling the medicine.
- Keep ivosidenib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused ivosidenib.

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 any appointments, call your care provider as soon as possible to reschedule your appointment.

Supportive Care to Prevent and Treat Side Effects

Description	Supportive Care Taken at Home
To help prevent or treat nausea and vomiting	
Other	

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Common Side Effects

Side Effect	Important Information
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection	Description: WBCs help protect your body from infections. A low WBC count increases your risk of getting infections. Recommendations: • Wash your hands often and bathe regularly. • Avoid crowded places and close contact with people who are sick. • Follow food safety and wound care advice from your care team. • Your care team may prescribe medicine to help your WBCs recover. Talk to your care team if you have: • Fever of 100.4°F (38°C) or higher • Chills • New or worsening cough or sore throat • Painful urination or signs of a urinary infection • Feeling much more tired than usual • Red, swollen, warm, or painful areas on the skin (possible skin infection)
Low Red Blood Cell (RBC) Count and Hemoglobin (Hgb) (Anemia)	Description: RBCs and Hgb carry oxygen to your body's tissues and remove carbon dioxide. Low RBC or Hgb (anemia) can make you feel weak, very tired, or look pale. 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
Fatigue	Description: Fatigue is a constant and sometimes strong feeling of tiredness. Recommendations: • Routine exercise can help reduce fatigue. Talk with your care team to find the right type and amount of activity for you. • Ask family and friends for help with daily tasks and for emotional support. • Try healthy ways to feel better, such as meditation, journaling, yoga, or guided imagery, to reduce anxiety and improve well-being. • Aim for 7 to 8 hours of sleep each night. Limit daytime naps to help you sleep better at night. • Do not drive, operate heavy machinery, or do other potentially dangerous activities if you are very tired. Talk to your care team if you have: • Tiredness that affects your daily life or prevents you from doing normal activities • Tiredness that does not get better with rest • Dizziness or weakness along with severe tiredness

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Your Body May Hold Too Much Fluid (Fluid Retention) Leading to Swelling (Edema)	Description: Fluid retention (edema) is swelling caused by excess fluid in body tissues, often seen in the legs, ankles, feet, hands, or abdomen. It can cause tightness, weight gain, and discomfort. 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. • 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 • Signs of shortness of breath or difficulty breathing • Swelling is persistent and 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.
Nausea and Vomiting	Description: Nausea is an uncomfortable feeling in your stomach or the need to throw up. You may or may not vomit. Recommendations: • Eat smaller, more frequent meals. • Avoid fatty, fried, spicy, or highly sweet foods. • Eat bland foods at room temperature and drink clear liquids. • If you vomit, start with small sips of water, broth, or other clear liquids. If these stay down, try soft foods (such as gelatin, plain cornstarch pudding, yogurt, strained soup, or strained cooked cereal) and gradually return to solid foods. • Your care team may prescribe medicine for these symptoms. Talk to your care team if you have: • Vomiting for more than 24 hours • Nonstop vomiting • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Blood or coffee-ground-like appearance in your vomit • Severe stomach pain that does not go away after vomiting
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

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Low Appetite	Description: Loss of appetite can lead to weight loss and low energy. Small changes in when and what you eat can help maintain strength and nutrition. Recommendations: • Be as active as you can. Do light physical activity before a meal (check with your care team before starting an exercise program). • Note times of day when your appetite is best and eat your largest meal then. • Eat 5–6 small meals or snacks each day. • Choose high-protein foods (beans, chicken, fish, meat, yogurt, tofu, eggs). Eat protein first during meals. • Choose higher-calorie foods (avoid “low-fat,” “fat-free,” or “diet” options when trying to gain/maintain weight). • If you feel full quickly, avoid drinking 30 minutes before a meal and drink liquids between meals; choose calorie-containing drinks rather than diet drinks. • Have a bedtime snack that’s easy to digest (for example, peanut butter and crackers). If you have reflux, wait at least 1 hour before lying down. • Try nutritious beverages (high-protein shakes or smoothies) if solid food is unappealing. • Ask your care team about liquid nutrition supplements and ways to add protein or calories (protein powder, yogurt, ice cream). Talk to your care team if you have: • Unintentional weight loss • Little or no appetite for several days • Excessive tiredness or low energy
Stomach-Area (Abdominal) Pain	Description: Abdominal pain is when you feel discomfort or pain in the belly area. Talk to your care team if you have: • Severe abdominal pain

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Diarrhea	Description: Diarrhea is loose, watery stools or more frequent bowel movements than usual. It can cause dehydration and weakness. Recommendations: • Keep track of how often you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids daily, unless your care team tells you otherwise. • Eat small meals of mild, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • If you have diarrhea, avoid high-fiber foods (such as raw vegetables, fruits, and whole grains), gas-producing foods (such as broccoli and beans), dairy (such as milk and yogurt), and spicy, fried, or greasy foods. • Your care team may recommend an antidiarrheal medicine such as loperamide (Imodium). Talk to your care team if you have: • 4 or more bowel movements than normal in 24 hours • Dizziness or lightheadedness while having diarrhea • Signs of dehydration (very thirsty, dry mouth, dizziness, or dark urine) • Bloody diarrhea
Kidney Problems	Description: Treatment can cause kidney problems, including damage to the kidneys and decreased kidney function. Your care team will monitor your kidney function during treatment. Recommendations: • Drink 8 to 10 glasses of water or other fluids each day, unless your care team tells you otherwise. • Your care team may give you fluids and electrolytes with your treatment. Talk to your care team if you have: • Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
Trouble Breathing and Cough	Description: Treatment may make you feel like it's a struggle to get enough air into your lungs. A cough is a reflex action that forcefully expels air from the lungs to clear the airways of irritants or mucus. Recommendations: • Stay hydrated by drinking plenty of fluids to help thin mucus. • Avoid irritants such as smoke, strong odors, and allergens. • Use humidifiers to add moisture to the air and soothe airways, and drink plenty of water. • Practice controlled breathing techniques, like pursed-lip breathing. • Elevate your head with extra pillows when resting or sleeping, if needed. • Limit physical exertion and take breaks during activities. • Tell your care team what your cough feels like and when it happens. • Keep your house clean by dusting and vacuuming regularly • Your care team may recommend medicine for cough. Talk to your care team if you have: • Trouble breathing • Chest pain or tightness • Cough

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Muscle or Joint Pain or Weakness	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. 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
Changes in Electrolytes and Other Laboratory Results	Description: Treatment may cause low levels of potassium, magnesium, and sodium, and high levels of uric acid in your blood. Your care team will do blood tests to check you for these changes and will treat you if needed. Talk to your care team if you have: • New or worsening muscle weakness or cramps • Irregular, fast, or pounding heartbeat, or chest pain • Severe dizziness, fainting, or lightheadedness • Severe constipation or stomach-area (abdominal) pain • Extreme fatigue • Muscle spasm, twitches, tremors, or cramps • Numbness or tingling in your fingers or toes • Nausea, vomiting, or loss of appetite • Seizures or fainting • New or worsening confusion, drowsiness, or trouble thinking • Severe headache or nausea/vomiting • Sudden weakness, unsteadiness, or trouble walking • Difficulty breathing • Sudden, severe joint pain, redness, or swelling (possible gout) • Severe flank or abdominal pain, blood in the urine, or difficulty urinating (possible kidney stone) • Little or no urine output or sudden weight gain from fluid • Fever, chills, or signs of infection • New or worsening kidney test results

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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Differentiation Syndrome (Boxed Warning)	Differentiation syndrome is a condition that affects your blood cells and may be life- threatening or lead to death. Differentiation syndrome in adults with AML and MDS has occurred as early as 1 day and up to 3 months after starting ivosidenib. If you develop signs and symptoms of differentiation syndrome, your care team may treat you with a corticosteroid medicine or a medicine called hydroxyurea and may monitor you in the hospital. • Fever of 100.4°F (38°C) or higher • Weight gain • Trouble breathing • Cough • Decreased urination • Swelling (especially in the hands, feet, or face) • Dizziness or lightheadedness
Changes in the Electrical Activity of Your Heart called QT prolongation	• Feel faint, lightheaded, or dizzy • Fast or irregular heartbeat

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.

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 may 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:
        - Take a pregnancy test before starting treatment.
        - Use an effective method of birth control during treatment with ivosidenib.
        - 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 with ivosidenib.
- **Do NOT breastfeed** during treatment and for 1 month after your last dose of ivosidenib.

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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.
- **Tell your care team about all your health problems.** This includes issues with your immune system, like Crohn's disease, ulcerative colitis, or lupus. Also, tell them if you have had an organ transplant, like a kidney or eye transplant. Let them know if you had a stem cell transplant from a donor, had radiation to your chest, or have a nerve problem like myasthenia gravis or Guillain-Barré syndrome.
- **You should not drink grapefruit juice or eat grapefruit during treatment with ivosidenib.** Grapefruit may increase the amount of ivosidenib in your blood.
- **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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Scan the QR code below to access this education sheet.

Important notice: The Association of Cancer Care Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), Network for Collaborative Oncology Development & Advancement, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources.

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