

Lirafugratinib

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is used for 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 abnormal type of fibroblast growth factor receptor 2 (FGFR2) gene to make sure lirafugratinib 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
Lirafugratinib (li-RA-fue-GRa-ti-nib): Lyrfigtu (leer-fig-too)	Slows down or stops the growth of cancer cells by blocking a specific protein that helps them survive.	Capsule(s) taken by mouth.

Treatment Administration and Schedule

Your lirafugratinib dosing instructions:

- Lirafugratinib comes in 2 capsule strengths: 20 mg and 30 mg.
- Your dose might differ, but lirafugratinib is typically taken as two 20 mg capsules and one 30 mg capsule (70 mg total dose) by mouth once daily.
- Take lirafugratinib 1 time a day, around the same time each day.
- Take lirafugratinib with or without food.
- Swallow lirafugratinib capsules whole. Do not open, break, or chew the capsules.
- Do not change your dose or stop taking lirafugratinib unless your care team tells you to.
- Your care team may tell you to change your dose, temporarily stop, or completely stop taking lirafugratinib if you develop certain side effects.

Treatment Administration and Schedule (Continued)

- If you miss a dose of lirafugratinib:
 - Take the missed dose as soon as possible within 4 hours.
 - If more than 4 hours have passed, skip the missed dose and take your next dose at your usual scheduled time.
 - Do not take more lirafugratinib than prescribed to make up for the missed dose.
- If you vomit after taking lirafugratinib, do not take another lirafugratinib. Take your regular dose of lirafugratinib the next day at the next scheduled time.
- If you take too much lirafugratinib, call your care team or go to the nearest hospital emergency room right away.

Storage and Handling of Lirafugratinib

- Store lirafugratinib at room temperature between 68°F and 77°F (20°C and 25°C).
- Lirafugratinib comes in blister cards in child-resistant packs (DosePaks™).
- Keep lirafugratinib and all medicines out of the reach of children and pets.
- Ask your care team how to safely throw away any unused lirafugratinib.

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	

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 infection. 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
Low Platelet Count (Thrombocytopenia)	Description: Platelets help your blood clot and wounds heal. A low platelet count increases your risk of bruising and bleeding. Recommendations: - Blow your nose gently and avoid picking it. - Brush your teeth gently with a soft toothbrush and keep good oral hygiene. - Use an electric razor for shaving and a nail file instead of nail clippers. - Avoid over-the-counter medicines that can increase bleeding risk (for example, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen). - Talk with your care team or dentist before medical or dental procedures — you may need to pause treatment. Talk to your care team if you have: - A nosebleed lasting more than 5 minutes despite pressure - A cut that continues to bleed - Heavy gum bleeding when brushing or flossing - Sudden or severe headache - Blood in your urine or stool - Blood in your spit after coughing
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

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
Mouth Problems	Description: Mouth problems can include changes in your sense of taste, dry mouth, trouble swallowing, and mouth sores. Recommendations: • Rinse your mouth after meals and at bedtime; rinse more often if sores develop. • Brush your teeth gently with a soft toothbrush or use a cotton swab after meals. • Use a mild, non-alcohol mouth rinse at least 4 times daily (after meals and at bedtime). Example: 1/8 teaspoon salt + 1/4 teaspoon baking soda in 8 oz warm water. • Avoid acidic, hot, spicy, rough, or crunchy foods and drinks that can irritate your mouth. • Avoid tobacco, alcohol, and alcohol-based mouthwash. • Your care team may prescribe medicines or mouth treatments to help with pain and healing. Talk to your care team if you have: • Painful mouth sores or throat pain • Trouble eating or significant weight loss
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

Constipation	Description: Constipation means hard, dry stools or fewer bowel movements than normal. It can cause discomfort or pain. Recommendations: • Track how often you have bowel movements each day. • Drink 8 to 10 glasses of fluids daily, unless your care team says otherwise. • Stay active and exercise regularly. • Eat more high-fiber foods (such as raw fruits, vegetables, and whole grains) unless advised otherwise. • Your care team may recommend laxatives such as polyethylene glycol (MiraLAX) or senna. Talk to your care team if you have: • Constipation lasting 3 or more days • No bowel movement 48 hours after using a laxative
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
High Blood Sugar (Hyperglycemia)	Description: Treatment may cause high blood sugar levels. Your care team may perform blood tests to check for these changes and treat you if needed. Recommendations: • Eat a well-balanced diet. • Limit sugary drinks and foods. • Eat smaller, more frequent meals. • Be physically active for at least 30 minutes most days. • Your care team may ask you to check your blood sugar at home. If you are already doing this, they may ask you to do it more frequently. Talk to your care team if you have: • Frequent urination • Drowsiness • Increased thirst • Loss of appetite • Blurred vision • Fruity smell on your breath • Confusion • Nausea, vomiting, or stomach pain • It becomes harder to control your blood sugar

Eye Problems	Description: Eye problems are common with this treatment and can sometimes be serious. These include blurred vision, new or increased floaters (spots or lines in your vision), flashes of light, sensitivity to light, or double vision. Rarely, eye problems can be severe and may cause partial or complete loss of vision. Recommendations: - You will need a full eye exam before starting treatment, every 2 months for the first 13 months, and every 4 months after that. - Your care team may send you to an eye care professional if you develop any new or worsening eye problems. - You may use artificial tear substitutes or lubricating eye gels to help prevent or treat dry eyes. - Wear sunglasses outdoors to reduce light sensitivity. - Use good lighting for reading and close work to reduce eye strain. - Avoid driving at night or in low light if you have vision changes. Talk to your care team if you have: - Eye pain - Eye redness - Eye swelling - Eye irritation - Increased tears - Feeling like something is in your eyes - Discharge from your eyes - Eye crusting - Sensitivity to light - Blurred vision - Vision changes
Hair Loss (Alopecia)	Description: Hair loss or thinning may begin days to weeks after treatment starts and usually grows back later. New growth can be a different color or texture and may not look the same as before. Recommendations: - Consider a short haircut before treatment and use scarves, hats, or wigs for comfort and confidence. - Keep your head covered outdoors to protect it from the sun and cold; apply sunscreen to your exposed scalp. - Use gentle haircare: mild shampoo, soft brush, and avoid heat styling and harsh treatments. - Ask your care team about wig prescriptions or resources for head coverings. Talk to your care team if you have: - No hair regrowth months after treatment ends - Concern about hair changes or need help finding a wig or support resources

Skin Problems	Description: Treatment can cause a rash with itchy, dry, red, or puffy skin. Recommendations: • Bathe or shower daily with warm (not hot) water and mild, unscented soap or body wash. • Pat your skin dry with a towel instead of rubbing. • Apply unscented lotion or moisturizing cream right after bathing to prevent dryness and cracking. • Use lip balm for dry or chapped lips. • Avoid direct sun when you can. Use a broad-spectrum sunscreen with a sun protection factor (SPF) of 30 or higher and reapply every 2 hours when outdoors. • Use unscented, gentle laundry detergent to reduce skin irritation. • Your care team may recommend medicine for skin problems. Talk to your care team if you have: • Skin rash • Raised red bumps • Redness of the skin • Very dry skin that may affect the mucous membranes (such as mouth and eyes)
Hand-Foot Syndrome (HFS)	Description: HFS causes dryness, thickening, swelling, or blisters of the skin on the palms of your hands and soles of your feet. HFS can lead to a loss of fingerprints, which could impact your identification. Recommendations: • Keep hands and feet moisturized with a non-scented moisturizing cream. • Applying urea 10% or 20% cream twice daily to the affected area may be helpful. • Avoid exposure to hot water on the hands and feet in showers or baths, or when doing dishes, as this may dry out the skin. • Avoid tight-fitting shoes or socks. • Avoid excessive rubbing of hands and feet unless applying lotion. • Wear gloves when working with your hands. Talk to your care team if you have: • Painful blisters or calluses on your hands or feet

Nail Changes	Description: Treatment can change how your fingernails and toenails look and feel. Nails may become discolored, ridged, brittle, thick, sore, or may lift or loosen from the nail bed. The skin around the nails can also become red, swollen, or painful. Recommendations: • Keep nails short and clean; trim carefully and file rough edges. • Wear comfortable shoes with room for your toes and soft socks. • Protect your hands and feet with gloves and closed-toe shoes when doing chores. • Avoid fake nails, gel/acrylic nails, and harsh chemicals (like strong nail polish removers). • Moisturize your hands, feet, and cuticles with fragrance-free cream. • Do not bite your nails or pick at the skin around them. Talk to your care team if you have: • Redness, swelling, warmth, or pain around a nail • Pus, drainage, or a bad smell from the nail area (signs of infection) • Nails that are very loose, lifting, or falling off • Nail changes that make it hard to walk or use your hands • Fever or chills along with nail or skin changes
High Phosphate Levels in Your Blood (Hyperphosphatemia) and Buildup of Minerals in Different Tissues in Your Body	Description: Treatment may cause high levels of phosphate in your blood. This may lead to the buildup of minerals, such as calcium, in different tissues in your body. Your care team will perform blood tests to check for these changes and will treat you if needed. Recommendations: • Read the Nutrition Facts on your food label. • Start a low-phosphate diet (limit dairy, cola, nuts, organ meats, processed foods). • Stay well hydrated. • Avoid phosphate-containing laxatives or supplements. • Your care team may prescribe changes in your diet or phosphate lowering therapy (such as sevelamer (Renvela) or calcium carbonate (Tums)). Talk to your care team if you have: • Muscle cramps, spasms, or numbness/tingling • Severe itching or new skin changes • Bone or joint pain • New or worsening irregular heartbeat, dizziness, or fainting • Little or no urine output
Low Sodium Levels in Your Blood (Hyponatremia)	Description: Treatment may cause low levels of sodium in your blood. Your care team will perform blood tests to check for these changes and will treat you if needed. Talk to your care team if you have: • New or worsening confusion, drowsiness, or trouble thinking • Severe headache or nausea/vomiting • Seizures or fainting • Sudden weakness, unsteadiness, or trouble walking • Difficulty breathing

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 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 lirafugratinib.
 - 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 lirafugratinib.
- **Do not breastfeed** during treatment and for 1 week after your last dose of lirafugratinib.

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.
- **Your skin may be sensitive to the sun or other forms of light (photosensitivity) during treatment with lirafugratinib.** Avoid or limit exposure to direct sunlight, sunlamps, and other sources of ultraviolet radiation during treatment. Use sunscreen or wear clothes that cover your skin if you need to be out in the sun.
- **You should not drink grapefruit juice or eat grapefruit during treatment with lirafugratinib.** Grapefruit may increase the amount of lirafugratinib 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

Updated Date: October 19, 2026

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 to gather information and develop this patient education guide. This guide is a summary of the medication, based on information provided by the drug manufacturer and other sources.

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