Leucovorin, Fluorouracil (5-FU), and Irinotecan

Patient Education Sheets
Understanding Your Cancer Treatment

Care Team Contact Information: _____

Pharmacy Contact Information: _____

Diagnosis: _____

- This treatment is often used for:
  - A type of bile duct cancer called cholangiocarcinoma (CCA)
  - Cancer of the stomach (gastric cancer), esophagus (esophageal cancer) or cancer located where the esophagus joins the stomach (gastroesophageal junction (GEJ) cancer)
  - Colon or rectal (colorectal) cancer (CRC)
  - Pancreatic cancer
- It may also be used for other reasons.

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

- This treatment is called by its acronym: FOLFIRI.
  - **FOL**: Leucovorin (**Fol**inic Acid)
  - **F**: **F**luorouracil
  - **IRI**: **Iri**notecan

Treatment Name	How the Treatment Works	How the Treatment is Given
Leucovorin (LOO-koh-VOR-in)	Helps fluorouracil (5-FU) bind more tightly to its target inside cancer cells. This allows it to stay and fight longer.	Infusion into a vein (intravenous (IV) infusion).
Fluorouracil (floor-oh-YOOR-uh-sil): Adrucil (ay-DROO-sil) • It is also called “5-FU”.	Stops cancer cells from making the instructions they need to grow and multiply, causing the cells to die.	Infusion into a vein (intravenous (IV) infusion). It is often given in two parts: first, a quick, concentrated dose (called a "bolus"), followed by a continuous infusion through a pump over 2 days (46 to 48 hours).
Irinotecan (I-rih-noh-TEE-kan): Camptosar (KAMP-toh-sar)	Slows down or stops the growth of cancer cells by interfering with the process that cancer cells use to make new cells.	Infusion into a vein (intravenous (IV) infusion).

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Treatment Administration and Schedule

Treatment is typically repeated every 2 weeks. This length of time is called a “cycle”.

- Sometimes your care team will remove the leucovorin, the bolus dose of fluorouracil (5-FU), or both from your treatment plan.

☐ **Option #1**

- Irinotecan is given on Day 1.
- Leucovorin is given on Day 1.
- Fluorouracil (5-FU) is given as a bolus on Day 1, followed by continuous infusion over 2 days (46 to 48 hours), ending on Day 3.

	Cycle 1							Next Cycle
Treatment Name	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**...**	**Day 14**	**Day 1**
Irinotecan	✓							✓
Leucovorin	✓							✓
Fluorouracil (5-FU) Bolus	✓							✓
Fluorouracil (5-FU) Continuous Infusion	→	→	→					→

☐ **Option #2**

- Irinotecan is given on Day 1.
- Leucovorin is given on Day 1.
- Fluorouracil (5-FU) is given as a continuous infusion over 2 days (46 to 48 hours), ending on Day 3.

	Cycle 1							Next Cycle
Treatment Name	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**...**	**Day 14**	**Day 1**
Irinotecan	✓							✓
Leucovorin	✓							✓
Fluorouracil (5-FU) Continuous Infusion	→	→	→					→

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☐ **Option #3**

- Irinotecan is given on Day 1.
- Fluorouracil (5-FU) is given as a continuous infusion over 2 days (46 to 48 hours), ending on Day 3.

Treatment Name	Cycle 1							Next Cycle
	Day 1	Day 2	Day 3	Day 4	Day 5	...	Day 14	Day 1
Irinotecan	✓							✓
Fluorouracil (5-FU) Continuous Infusion	→	→	→					→

Appointments

Appointments may include regular check-ups with your care team, treatment appointments, 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 Given at the Clinic or Hospital	Supportive Care Taken at Home
To help prevent or treat diarrhea		
To help prevent or treat nausea and vomiting		
To help prevent hand foot syndrome (HFS)		
Other		

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Common Side Effects

Side Effect	Important Information
Diarrhea (Boxed Warning)	Description: Diarrhea is when you have loose, watery bowel movements more often than usual. With irinotecan, diarrhea may be either "early" or "late". Early diarrhea starts less than 24 hours after your dose of irinotecan. Late diarrhea starts more than 24 hours after your dose of irinotecan. Early and late diarrhea are treated differently because they happen for different reasons. Recommendations: • If you have early diarrhea, your care team may give you a medicine called atropine. • Have loperamide (Imodium) ready at home. • If you have late diarrhea, your care team will tell you how often to take loperamide. • Keep track of how many times you go to the bathroom each day. • Drink 8 to 10 glasses of water or other fluids every day, 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 eating high-fiber foods (such as raw vegetables, fruits, and whole grains), foods that cause gas (such as broccoli and beans), dairy foods (such as yogurt and milk), and spicy, fried, and greasy foods. Talk to your care team if you have: • Diarrhea for the first time during treatment • Black or bloody stools • Symptoms of dehydration such as lightheadedness, dizziness, or faintness • Inability to take fluids by mouth due to nausea or vomiting • Inability to get diarrhea under control within 24 hours
Low White Blood Cell (WBC) Count (Neutropenia) and Increased Risk of Infection (Boxed Warning)	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 (possible skin infection)

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Low Platelet Count (Thrombocytopenia) (Boxed Warning)	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) (Boxed Warning)	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

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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 Sores or Irritation (Mucositis or Stomatitis)	Description: Treatment can irritate the lining of the mouth. In some cases, this can cause redness, sores, pain, and swelling. 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
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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<table>
<tr><td>Nausea and Vomiting</td><td>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</td></tr>
<tr><td>Low Appetite</td><td>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 or 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</td></tr>
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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
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
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; use sunscreen on your uncovered 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

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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
Watery Eyes and Eye Irritation	Description: Fluorouracil (5-FU) can cause very watery eyes (excessive tearing) and other eye problems. Your eyes may constantly water, feel irritated or sore, or look red, and you may notice skin irritation around the eyelids. Recommendations • Your care team may recommend using artificial tears or lubricating eye drops to keep your eyes comfortable. • Gently blot (do not rub) tears from your eyes and eyelids with a soft tissue. • Keep the skin around your eyes clean and dry; avoid makeup or eye creams that irritate your eyes. • Wear sunglasses outdoors to protect your eyes from wind and sun. Talk with your care team if you have: • Constant or worsening watery eyes that interfere with daily activities • Red, swollen, or painful eyelids, or skin changes or rash around the eyes • Eye redness with pain, burning, or a gritty feeling that does not improve • Blurred vision, trouble seeing, or new light sensitivity • Signs that tears are not draining properly (eyes always full of tears, tears running down your face most of the time)

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Select Rare Side Effects

Side Effect	Talk to Your Care Team if You Have Any of These Signs or Symptoms
Heart Problems	Fluorouracil (5-FU) can sometimes affect the heart. This may cause chest pain (angina) or, less often, more serious heart problems such as heart attack, abnormal heart rhythms, heart failure, or fluid in the lungs. These usually happen within the first few days of treatment, often during the first cycle. Call your care team right away (or seek emergency care) if you have: • Chest pain, pressure, tightness, or discomfort (may spread to arm, neck, jaw, or back) • Shortness of breath or trouble breathing, with or without chest pain • Fast, slow, or irregular heartbeat, pounding or fluttering in your chest • Sudden dizziness, fainting, or feeling like you might pass out • New or sudden swelling in your legs, ankles, feet, or sudden weight gain • Sudden severe fatigue, weakness, sweating, or nausea
Lung Problems	• Cough • Shortness of breath • Chest pain or chest tightness
Dizziness or Changes in Vision	These symptoms may happen within 24 hours after your dose of irinotecan. • Dizziness • Lightheadedness • Spinning sensation (vertigo)
Kidney Problems	• Decrease in your amount of urine • Blood in your urine • Swelling of your ankles • Loss of appetite
Extravasation	Extravasation happens when medicine that is supposed to go into a vein leaks out into the tissues around it. This can cause pain, swelling, and damage to the skin and tissues. • Pain, burning, or stinging at the infusion site • Swelling, redness, or blistering around the site • Coolness or numbness in the area • Decreased blood flow or tissue damage, potentially leading to ulcers or tissue death in severe cases
Infusion-Related Reactions	• Chills or shaking • Itching, rash, or flushing • Trouble breathing, wheezing, or tongue swelling • Dizziness or feeling faint • Feeling of impending doom • Fever of 100.4°F (38°C) or higher • New or severe pain in your back or neck
Allergic Reactions	Get emergency medical help right away if you develop any of the following signs or symptoms: • Swelling of your lips, mouth, tongue, or throat • Trouble breathing or swallowing • Raised red areas on your skin (hives) • A very fast heartbeat • You feel dizzy or faint

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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:
        - Take a pregnancy test before starting treatment.
        - Use an effective method of birth control during treatment, for 3 months after your last dose of fluorouracil (5-FU), and for 6 months after your last dose of irinotecan.
        - 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 FOLFIRI.
- **Do NOT breastfeed** during treatment with FOLFIRI and for 7 days after your last dose of irinotecan.

Handling Body Fluids and Waste

Some drugs you receive may stay in your urine, stool, sweat, or vomit for many days after treatment. Because many cancer drugs are toxic, your body waste may also be dangerous to touch. To help protect yourself, your loved ones, and the environment, **follow these instructions** for at least **48 hours** after each dose of **FOLFIRI:**

- People who are pregnant should avoid touching anything that may be soiled with body fluids from the patient.
- You can use your usual toilet. Always close the lid and flush to discard all waste. If you have a low-flow toilet, flush twice.
- If the toilet or seat is soiled with urine, stool, or vomit, clean the surface after each use before others use it.
- Wash your hands with soap and water for at least 20 seconds after using the toilet.
- If you need a bedpan, inform your caregiver so they can wear gloves and assist with cleanup. Wash the bedpan with soap and water daily.
- If you cannot control your bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb waste.
- Wash any skin exposed to body waste with soap and water.
- Wash soiled linens or clothing separately from other laundry. If you don't have a washer, place them in a plastic bag until they can be washed.
- Wash your hands with soap and water after touching soiled linens or clothing.

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Additional Information

- **Boxed Warning: People with deficiencies in the enzyme dihydropyrimidine dehydrogenase (DPD) may experience serious side effects.**
  People with certain changes in a gene called "DPYD" may have a deficiency of the DPD enzyme. Some of these people may not produce enough DPD enzyme, and some of these people may not produce the DPD enzyme at all.
  - People who do not produce enough DPD enzyme are at increased risk of serious and potentially life-threatening side effects during treatment with fluorouracil (5-FU).
  - Call your care team right away if you develop any of the following symptoms and they are severe, including:
    - Sores of the mouth, tongue, throat, and esophagus
    - Diarrhea
    - Low white blood cell counts
    - Nervous system problems
- **People with deficiencies in the enzyme UDP-glucuronosyltransferase 1A1 may experience serious side effects.**
  People with certain changes in a gene called "UGT1A1" may have a deficiency of the UDP-glucuronosyltransferase 1A1 enzyme.
  - People with certain changes in the UGT1A1 gene are at increased risk of sudden side effects that come on early during treatment with irinotecan and can be serious and sometimes lead to death.
  - Call your care team right away if you develop any of the following symptoms and they are severe, including:
    - Diarrhea
    - Low white blood cell counts
- **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.
- Talk with your care team about whom to contact if your **fluorouracil (5-FU) pump doesn't work properly**. Do not ignore any pump alarms.
- **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: July 9, 2026

Scan the QR code below to access this education sheet.

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