







FOLFIRI + CETUXIMAB

Name of the regimen and cancer drugs

Your care team may refer to your treatment as "FOLFIRI" plus cetuximab. FOLFIRI plus cetuximab consists of 4 different anticancer therapies.

- FOL: Leucovorin (LOO koh VOR in); Folinic acid
- F: 5-FU or fluorouracil (floor oh YOOR uh sil); Adrucil®
- IRI: Irinotecan (I rih noh TEE kan); Camptosar®
- Cetuximab (seh TUK sih mab); Erbitux®

Common uses

This regimen is most commonly used to colon cancer and rectal cancer, but may be used for other diagnoses.

Treatment schedule

Your treatment will be given into your vein through an intravenous (IV) line called a central venous catheter. A central venous catheter, or central line is a long, flexible IV tube that empties into a very large vein next to the heart. Talk with your care team to see which type of central line will be best for you and your treatment.

Each FOLFIRI + cetuximab treatment is repeated every 14 days. This is known as one cycle. Your treatment may be given for a set number of cycles, or it will keep going until the drug, or drugs, stop working or you have side effects which stop you from continuing treatment.

Leucovorin IV on day 1
Fluorouracil (5-FU) IV push on day 1
Fluorouracil (5-FU) continuous IV infusion over 46 hours beginning on day 1 and ending on day 3
Irinotecan IV on day 1
Cetuximab IV on day 1

Drug	Cycle 1 Day	1	2	3	4	5	6	 14	Cycle 2 Day 1
Leucovorin									
Fluorouracil IV push									
Fluorouracil IV infusion									
Irinotecan									
Cetuxii	mab								









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Other medications

Other medications may be ordered for you to prevent or treat certain side effects. These include:

	Instructions:
Growth factors	Growth factors, like filgrastim, pegfilgrastim, and others, are medications used to treat neutropenia and prevent infections. Neutropenia is a condition where there are lower-than-normal white blood cells caused by some type of chemotherapy. Growth factors help the bone marrow to make more white blood cells.
Medications to prevent side effects	You will receive medications to prevent side effects just before your cancer treatment. You may also get prescriptions for other medications to take at home, as below:
Anti-nausea medications	You will receive medications to prevent nausea just before your cancer treatment. You may also get prescriptions for other medications to take at home, as below:

Possible drug interactions

- □ FOLFIRI + cetuximab may interact with other drugs you are taking. Please inform your care providers of all prescription medicine, over-the-counter medications, vitamins, and herbal products that you take.
- ☐ Talk with your care provider or pharmacist before taking new medications, supplements, or receiving any vaccines.









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Common Side Effects

Common side effects that have been known to happen in patients receiving FOLFIRI + cetuximab are listed in the left side of this table. In some instances, the side effects may be reported less often but are still important to discuss. This table does not list all the known side effects for this therapy, only the ones that are experienced most often. Not every patient experiences every known side effect of a drug; even if you are taking the same drug as another patient, you may experience different side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Decreased white blood cells (WBCs) and increased risk for infection	Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection: • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe often for good personal hygiene. Contact your care team if you experience any signs or symptoms of an infection such as: • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning when peeing • Tiredness that is worse than normal • A sore that becomes red, is draining, or does not heal. Check with your care team before taking any medicine for a fever or chills.
Decreased platelet count and increased risk of bleeding	Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual. Use caution to avoid bruises, cuts, or burns. Blow your nose gently and do not pick your nose Brush your teeth gently with a soft toothbrush and maintain good oral hygiene When shaving use an electric razor instead of razor blades Use a nail file instead of nail clippers Call your care team if you have bleeding that won't stop. Examples include: A bloody nose that bleeds for more than 5 minutes despite pressure A cut that continues to ooze despite pressure Gums that bleed a lot when you floss or brush
	Continued on the next page









Possible Side Effect	Management
Decreased platelet count and increased	Seek medical help right away if you have any severe headaches, blood in your urine or stool, coughing up blood, or bleeding that you cannot stop or lasts a long time.
risk of bleeding	You may need to take a break or "hold" your medication for medical or dental procedures.
(continued)	Talk to your care team or dentist before any scheduled procedures.
Decreased hemoglobin, part of the red blood cells that carry iron and oxygen	Your hemoglobin should be checked by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily. Try to get 7 to 8 hours of sleep per night Avoid operating heavy machinery if you feel too tired Find a balance between "work" and "rest" Stay as active as possible, but know that it is okay to rest as needed, too You might notice that you are more pale than usual Let your care team know right away if you have: Shortness of breath Dizziness Fast or abnormal heartbeat Headache
Rash or itchy skin	 Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness and wear loose fitting clothing. Avoid using perfumes and cologne as these products may increase rash symptoms. Avoid being in the heat for long periods of time. Your provider may recommend an over-the-counter antihistamine or a topical cream. Sunlight can make symptoms worse. Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultra-violet) radiation occurs between the hours of 10am and 4pm. Wear long-sleeved clothing, with UV protection if possible. Wear broad-brimmed hats. Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. Use lip balm with at least SPF 30. Avoid tanning beds.
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Possible Side Effect	Management
Acne-like rash	 A rash that looks like acne may happen on your face, chest, and upper back while taking this medication Your doctor may prescribe medication to help prevent or manage the rash If you do get a rash, keep the area around the rash clean and dry Check with your care team before using anything to treat it Do not use over-the-counter acne treatments such as benzoyl peroxide or salicylic acid and soaps containing alcohol Wash with a mild, moisturizing soap; avoid long, hot baths or showers After washing, pat skin dry; avoid vigorous rubbing Oatmeal baths and unscented moisturizers may help with itching Sunlight can make symptoms worse Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultra-violet) radiation occurs between the hours of 10am and 4pm. Wear long-sleeved clothing, with UV protection if possible Wear broad-brimmed hats Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle Use lip balm with at least SPF 30 Avoid tanning beds
Diarrhea (loose and/ or urgent bowel movements)	 Monitor how many bowel movements you have each day. Drink 8-10 (8-ounce) glasses of water or fluid each day unless your care team has asked you to limit your fluid intake. Eat small, frequent meals throughout the day rather than a few large meals. Eat bland, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). Avoid high fiber foods, such as raw vegetables and fruits and whole grains. Avoid foods that cause gas, such as broccoli and beans. Avoid foods with lactose, such as yogurt and milk. Avoid spicy, fried, and greasy foods. Contact your care team if: The number of bowel movements you have in a day increases by 4 or more. You feel dizzy or lightheaded. Your care team may recommend an over-the-counter medication or prescribe something to help manage your symptoms.
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Possible Side Effect	Management
Nausea or vomiting	 Take all medications as prescribed to help prevent and lessen symptoms of nausea and vomiting. Eat and drink slowly. Drink 8-10 (8-ounce) glasses of water and/or fluid (soup or broth) each day unless your care team has instructed you to limit your fluid intake. Eat small, frequent meals throughout the day rather than a few large meals. Eat bland foods; avoid spicy, fried, and greasy foods. Avoid intense exercise immediately after eating. Don't lay down right away after eating. Wear loose-fitting clothing for comfort. Avoid strong odors. Consider getting fresh air and try deep breathing. Let your care team know if you have nausea or vomiting. Your care team may prescribe medication to help with the symptoms.
Mouth irritation or sores	 Practice good mouth care. Rinse your mouth after meals and at bedtime, and more frequently if you develop sores in your mouth. Brush your teeth with a soft toothbrush or cotton swab after meals. Use a mild non-alcohol mouth rinse at least 4 times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water. Avoid acidic, hot or spicy foods and beverages, and rough foods that might irritate the mouth. If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol. Call your care team if you experience pain or sores in your mouth or throat.
Changes in electrolytes and other laboratory values • Low magnesium levels • Low calcium levels	Changes in some lab values may occur and will be monitored by a simple blood test. • You may not feel any symptoms if the changes are mild and they usually are not a sign of a serious problem • More severe changes may occur which can be a sign of a serious problem Notify your care team if you have any of the following: • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness
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Possible Side Effect	Management					
Changes in electrolytes and other laboratory values • Low magnesium levels • Low calcium levels (continued)	Notify your care team if you have any of the following: Swelling of your legs or feet Red or brown colored urine					
Nail changes	 Nails on fingers and toes may look swollen and reddened and may grow ridges Skin/Nail changes: report any rashes, dryness or scaling to care provider, use mild soaps and rinse well, avoid hot water, use alcohol free oil-based moisturizers, report any darkening or peeling skin or any changes to the nail Usually this change starts at the cuticle and may affect the skin around the nail Wear gloves when cleaning or doing dishes, or working in the garden Keep nails trimmed and hands clean Biting, chewing, or picking at your nails can increase the risk of getting an infection Talk to your care team if you notice any changes in your nails 					
Fatigue	 You may be more tired than usual or have less energy Stay as active as possible, but know it is okay to rest as needed Try to do some type of moderate activity every day Conserve your energy. Plan your activities and do them at a time of day when you feel a bit more energetic Follow a healthy diet and stay hydrated Accept help from family and friends Find healthy ways to manage stress, such as meditation, journaling, yoga, and guided imagery Develop good sleeping habits, limit napping during the day to help you sleep better at night Avoid operating heavy machinery if you feel too tired Contact your care team if you experience extreme fatigue that prevents you from doing your normal daily activities 					









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Rare but serious side effects

Harc	but serious side circuis
	Cetuximab and fluorouracil can cause your heart to stop beating effectively. Seek medical attention right away if you begin feel chest pain, shortness of breath, weakness, dizziness or light headedness, or heart palpitations.
	Fluorouracil can cause changes to your balance, confusion, dizziness, or headache.
car	Dihydropyrimidine dehydrogenase (DPD) deficiency is a rare genetic condition where the body cannot break down certain ncer treatments, leading to severe side effects. Talk to your doctor to see if you should be tested.
CO	Irinotecan and cetuximab may cause harm to your lungs. Inform your care team of any new or worse difficulty breathing, ugh, shortness of breath, chest pain or fever. Your provider may stop treatment if your lungs are affected.
	Cetuximab can rarely cause an infusion reaction. During your treatment, let the nurse know right away if any of these mptoms happen: chills or shaking, dizziness, fever, itchiness or rash, flushing, difficulty breathing, wheezing, sudden back in, or feeling faint.
	Cetuximab may deplete certain electrolytes. Speak to your care team to know when you need to have laboratory tests done monitor your electrolyte levels.
If you	u experience ANY new, worsening, or uncontrolled side effects, call your care team immediately.
	(INSTITUTIONAL CONTACT INFO)
Hand	ling body fluids and waste
drı FO	me of the drugs you receive may be present in urine, stool, sweat, or vomit for many days after treatment. Many cancer ugs are toxic, your bodily waste may also be toxic and can be dangerous to come into contact with. Once you have started LFIRI + cetuximab, follow the instructions below for at least two days after your treatment. This is to keep you, your loved es, and the environment as safe as possible.
	Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
	Toilet and septic systems
	 You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
	If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surface after every use before other people use the toliet.
	Wash hands with soap and water after using the toilet for at least 20 seconds.
	If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
	If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
	Wash any skin that has been exposed to body waste with soap and water.
	Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.

☐ Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.









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Intimacy, sexual activity, contraception, and fertility

This treatment may cause changes that can affect intimacy and sexuality, including desire and body image. Maintaining physical closeness and/or intimacy with loved ones can be continued during treatment. Holding hands, hugging, and kissing can be done safely. It is recommended that you talk to your care team about any restrictions or questions you may have.

Some treatments can influence the ability to have children, also known as fertility. If you're interested in preserving fertility, talk to your care team before treatment. Ask your healthcare provider to determine when it is safe to become pregnant after your treatment. Patients of reproductive ability should not become pregnant or get their partners pregnant while receiving FOLFIRI + cetuximab. Some of the drugs you receive may be present in semen and vaginal secretion for many days after treatment. You should use barrier devices, such as condoms, during sexual activity to limit exposure to body fluids.

Talk to your care team about birth control. Not all options may be right for your treatment or cancer. Effective
contraception could include one or more of the following: barrier methods (e.g. condoms), hormone methods (e.g. birth
control pills), or surgery.

Tell your care team if you become pregnant or plan to breastfeed.

Additional resources

Product website:

Cetuximab (Erbitux): https://www.erbitux.com/

Prescribing information:

Cetuximab (Erbitux): https://uspl.lilly.com/erbitux/erbitux.html#pi

Irinotecan (Camptosar): https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/020571s048lbl.pdf

Leucovorin: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/040347s010lbl.pd

Fluorouracil or 5-FU (Adrucil): https://www.accessdata.fda.gov/drugsatfda docs/label/2016/012209s040lbl.

pdf

Additional instructions

Updated - September 29, 2023

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, 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 therapy derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this therapy and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this therapy by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual receiving therapy. All decisions related to receiving this therapy should be made with the guidance and under the direction of a qualified healthcare professional.

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