

Patient Treatment Information

Irinotecan + Cetuximab

Your chemotherapy treatment is called irinotecan + cetuximab. It is commonly used to treat colorectal cancer and has also been used to treat other diseases. Irinotecan + cetuximab is made up of two drugs:

- Irinotecan (eye-rye-no-TEE-can) or Camptosar® (CAMP-toe-sar)
- Cetuximab (se-TUX-i-mab) or Erbitux® (ER-bi-tux)

Irinotecan is a chemotherapy drug that prevents cancer cells from dividing and growing, and can eventually cause the cancer cells to shrink and die. Cetuximab is a new type of drug, called a monoclonal antibody, which targets cancer cells more precisely than chemotherapy drugs.

What Do I Need to Know Before Starting Treatment?

Be sure to tell your healthcare provider about any prescription or over-the-counter products you are taking, including dietary supplements, vitamins, herbal medicines and homeopathic remedies.

Use an effective birth control method while you are being treated with irinotecan + cetuximab, and for six months after your last dose of cetuximab. These drugs can cause harm to a fetus, so be sure to tell your healthcare provider right away if you or your partner become pregnant.

Avoid breastfeeding during treatment and for two months after your last dose of cetuximab. It is not known if these drugs pass into breast milk.

Some chemotherapy drugs can cause sterility. Talk with your healthcare provider about your options if you want to have children in the future.

Do not get any immunizations or vaccinations while you are being treated without the approval of your healthcare provider.

What Do I Need to Know Before Starting Irinotecan + Cetuximab?

Irinotecan commonly causes diarrhea, which can occur early or late in your treatment. Tell your healthcare provider if you are taking a laxative or stool softener since these medicines make diarrhea worse.

- Early diarrhea occurs within 24 hours of treatment. Tell your healthcare provider immediately if you have watery eyes, a runny nose, increased salivation, stomach cramps, flushing or sweating during or after your treatment. If you have early diarrhea, you may need to be treated with a drug called atropine.
- Delayed diarrhea occurs one to several days after treatment. It usually peaks at about eleven days after your treatment. It can be very severe and can lead to dehydration and hospitalization.
- You should have loperamide (Imodium A-D) available before you begin treatment so you can start taking it immediately at the first sign of loose or more frequent stools. The recommended dose on the loperamide package is not enough to treat diarrhea caused by irinotecan.
- Unless otherwise directed by your healthcare provider, take 4 mg (two tablets or capsules) of loperamide followed by 2 mg (one tablet or capsule) every two hours until you are diarrhea-free for at least 12 hours. At night, take 4 mg (two tablets or capsules) every four hours. Call your healthcare provider if the diarrhea continues for more than one day or if you feel lightheaded, dizzy or faint.

In rare cases, irinotecan can cause inflammation of the large intestine, which can cause complications such as ulceration, bleeding and infection. Tell your healthcare provider if you have sudden abdominal pain or rectal bleeding. You may be given antibiotics if necessary.

Side effects can be more severe in older patients and in those who have had radiation therapy to the pelvis or abdomen. Tell your healthcare provider if you have ever had radiation.

In rare cases, irinotecan can cause a severe allergic reaction. Tell your healthcare provider if you notice a skin rash, itching, chills, redness of the face, dizziness, headache or shortness of breath.

In rare cases, irinotecan can cause severe kidney problems. This is more common in patients who become dehydrated because of severe diarrhea or vomiting.

Irinotecan can cause irritation if it accidentally leaks out of the vein. Tell your healthcare provider right away if you have redness, pain, burning or swelling around the injection site during your treatment.

Cetuximab often causes skin problems, such as an acne-like rash, dry skin, redness and swelling. Sun exposure can make symptoms worse. Try to stay out of direct sunlight and wear protective clothing, sunglasses and sunscreen with an SPF of 30 or higher when outside during treatment and for two months after your last dose of cetuximab. (See “What Are the Possible Side Effects” in the chart below.)

Cetuximab can cause an infusion reaction, usually with the first dose. Your healthcare provider will give you medicine before your treatment to reduce your risk of an allergic reaction. Tell your healthcare provider right away if you develop a rash, itching, chest tightness or have trouble breathing while you are taking cetuximab. In rare cases, the reaction can be severe and life-threatening.

In extremely rare cases, cetuximab can cause severe lung disease. Tell your healthcare provider if you have trouble breathing while you are taking cetuximab.

Your treatment can interact with other substances, including:

- Ketoconazole (Nizoral®), fluconazole (Diflucan®) or itraconazole (Sporanox®)
- St. John’s wort
- Cimetidine (Tagamet®)
- Diltiazem, verapamil or nifedipine
- Phenytoin (Dilantin®), phenobarbital (Luminal®) or carbamazepine (Tegretol®)
- Rifampin or rifabutin
- Atazanavir (Reyataz®)
- Diuretics

Please note this list is a summary and does not contain all possible drug interactions. Contact your healthcare provider if you are taking any medications that can interact with your treatment.

You should not take this treatment if you are allergic to irinotecan, cetuximab or any components of these drugs.

How Is the Treatment Given?

Your healthcare provider will give you your treatment by injection into a vein. The dose you receive will be based on your weight and height. Your healthcare provider will determine the number of treatments you receive.

You may be given medicines to help prevent and control nausea and vomiting before you receive your treatment. These medicines may be given either by mouth or by injection into a vein.

If you are given any medicine to take at home, do not share it with others. Sharing this medication with anyone else could be harmful.

When Should I Call My Healthcare Provider?

Call your healthcare provider right away if you have any of the following symptoms:

- Shaking chills or fever of 100.5 degrees F or higher
- Unusual bleeding, easy bruising or pinpoint red spots on your skin
- Vomiting that is severe or lasts several hours
- Painful or frequent urination or blood in your urine
- Diarrhea that causes an additional four bowel movements a day, diarrhea that lasts more than one day, diarrhea at night or diarrhea with fever, cramps or bloody stools
- Irregular or rapid heart beat, chest pain, chest tightness or shortness of breath
- Dizziness or feeling lightheaded
- Inability to eat or weight loss

What Are the Possible Side Effects?

All drugs can cause side effects, but every person reacts differently to each drug. The following chart lists the possible side effects that can occur with your treatment, how to recognize and minimize symptoms and possible treatments. The side effects are grouped by how often the side effect occurs: Common (occurs in more than 25 percent of patients), Less Common (occurs in 5 to 25 percent of patients) or Rare (occurs in less than 5 percent of patients).

| Side Effect | How to Minimize Side Effect | Possible Treatments |
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| <p>Rash (Common. Symptoms are generally mild to moderate.)</p> <ul style="list-style-type: none"> • Acne-like rash • Usually occurs within the first two weeks of treatment but can occur as early as one week and as late as eight weeks after treatment begins • Usually mild and short-lived • Usually occurs on the face, upper chest and back but may also appear on the arms or legs • May be itchy or dry • May appear as a flat, discolored area on the skin or as a small raised bump | <ul style="list-style-type: none"> • Avoid prolonged exposure to heat. • Use creams or moisturizers regularly. Try wearing cotton gloves on your hands. • Avoid using perfume, cologne or aftershave since these products can be irritating to the skin. | <ul style="list-style-type: none"> • Your healthcare provider may prescribe creams (mild steroids, antihistamines or antibiotics) or an oral antibiotic called minocycline to help treat the rash. • The rash may improve on its own without any treatment. |
| <p>Risk of Infection (Common)</p> <ul style="list-style-type: none"> • Fever and chills • Painful urination • Sore throat and cough • Nasal congestion • Swelling or redness of the skin at the site of a wound | <ul style="list-style-type: none"> • Wash your hands often. • Brush and floss your teeth daily. • Clean cuts right away with warm water, soap and antiseptic. • When your white blood cell count is low, stay away from crowds and people with colds or other illnesses. | <ul style="list-style-type: none"> • You may be given medicine to increase your white blood cell count. • You may be given an antibiotic to treat or prevent infection. • Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy. |
| <p>Nausea/Vomiting (Common. Symptoms are generally mild to moderate.)</p> <ul style="list-style-type: none"> • Feeling queasy or sick to your stomach | <ul style="list-style-type: none"> • Eat small, frequent meals and bland foods—such as bananas, rice, applesauce and toast. • Eat food cold or at room temperature so the smell of food will not bother you. • Avoid fried, spicy or fatty foods. • Eat and drink slowly. • Drink plenty of liquids during the day, but to avoid bloating, drink small amounts of fluid during meals. | <ul style="list-style-type: none"> • You will be given medicine to help reduce nausea and vomiting. |
| <p>Mouth Sores and Pain (Common. Symptoms are generally mild.)</p> <ul style="list-style-type: none"> • Pain, swelling and redness of the mouth, tongue and throat • “Coated tongue” • Difficulty talking, swallowing or eating • Bleeding ulcers and infection | <ul style="list-style-type: none"> • Brush teeth two to four times a day using a soft bristle brush and fluoride toothpaste. • Use non-waxed dental floss daily. • Ask your healthcare provider to recommend a mouthwash that does not contain alcohol. • Sip water during the day and use sugar-free candy or gum to keep your mouth wet. • Eat food cold or at room temperature. • Eat soft or pureed food • Avoid food that is acidic, spicy, salty, dry or rough, such as toast. | <ul style="list-style-type: none"> • You may be given medicine to help treat pain. • You may be given medicine to treat fungal or viral infections. |
| <p>Diarrhea (Common. Symptoms are generally mild.)</p> <ul style="list-style-type: none"> • Loose or watery stools several times a day • Abdominal cramping, gas and bloating | <ul style="list-style-type: none"> • Eat small, frequent meals and bland foods—such as bananas, rice, applesauce and toast. • Avoid caffeine; alcohol; raw fruits and vegetables; raw eggs; undercooked meats; spicy, fatty and greasy foods; milk and dairy products; foods that cause gas, such as beans and other legumes; high fiber and high-fat foods; foods left un-refrigerated for more than two hours (one hour for egg dishes and cream or mayonnaise-based foods); bulk laxatives; and stool softeners. | <ul style="list-style-type: none"> • Drink eight to ten glasses of clear liquids every day. • Your healthcare provider may prescribe medicine to help treat diarrhea. |

| Side Effect | How to Minimize Side Effect | Possible Treatments |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Anemia (Less Common) <ul style="list-style-type: none"> Fatigue or weakness Dizziness Pale skin Feeling out of breath Feeling cold | <ul style="list-style-type: none"> Plan rest periods throughout the day. Organize daily activities so that you conserve your energy. Try to eat a well balanced diet and drink plenty of fluids. Stand up slowly to avoid getting dizzy. | <ul style="list-style-type: none"> You may be given medicine to increase your red blood cell count. Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy. |
| Bleeding (Less Common) <ul style="list-style-type: none"> Unusual bleeding, easy bruising Black or tar-like stools Blood in your urine Pinpoint red spots on your skin Bleeding gums or nosebleeds | <ul style="list-style-type: none"> Avoid aspirin and aspirin-like drugs, such as ibuprofen. Use caution with sharp objects, such as razors and nail cutters. Avoid activities that can cause cuts, bumps and bruises. | <ul style="list-style-type: none"> You may be given medicine to increase your platelet count. Your healthcare provider may decrease your chemotherapy dose or delay further chemotherapy. |

What Are The Other Possible Side Effects?

The following chart lists additional side effects found with the individual drugs in this treatment. It does not list all possible side effects. For more information, talk with your healthcare provider.

| Common Side Effects | Less Common Side Effects | Rare Side Effects |
|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> Fever | <ul style="list-style-type: none"> Fatigue Low blood pressure Weakness | <ul style="list-style-type: none"> Abdominal pain Shortness of breath |

Notes

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References:

- Vincenzi et al. Cetuximab and irinotecan as third-line therapy in advanced colorectal cancer patients: a single centre phase II trial. *British Journal of Cancer* 2006. 94, 792 – 797.
- Cunningham D, et al. Cetuximab monotherapy and cetuximab plus irinotecan in irinotecan-refractory metastatic colorectal cancer. *NEJM* 2004; 351:337-345.
- Scope A et al, Randomized double-blind trial of prophylactic oral minocycline and topical tazarotene for cetuximab-associated acne-like eruption. *J Clin Oncol.* 2007; 25:5390-5396.