Ask about your options.
Find out if ERBITUX® is right for you.

Open communication with your healthcare team is important from the moment of diagnosis and continues beyond completion of treatment.

These questions can help you start a conversation with your doctor about the treatments that are available to you, what to expect, and if ERBITUX might be an option for you.

ERBITUX®
CETUXIMAB
Injection for Intravenous Infusion
100 mg/50 mL & 200 mg/100 mL vials

What are my treatment options?

- In metastatic colorectal cancer, what is *RAS* testing? Might it affect my treatment options? If so, how?
- How do these treatments work? Why are you considering them for me?
- In metastatic colorectal cancer, is genetic testing important? Why or why not?

What is ERBITUX?

- How is ERBITUX given?

Could ERBITUX be right for me?

What kind of support is available for me once I start treatment?

- Who can I speak with about getting help with the cost of ERBITUX?
- Are there resources, support groups, and services to help people with cancer like me?

Notes

INDICATION

Metastatic colorectal cancer

- ERBITUX® (cetuximab) is approved for the treatment of certain patients who have colorectal cancer that has spread to other parts of the body. Only patients whose tumors are *KRAS* wild-type (which means they have a *KRAS* mutation-negative gene), and whose tumors have a protein called epidermal growth factor receptor (EGFR), should receive ERBITUX. An FDA-approved test is used to determine if tumors have these particular traits. Treatment with ERBITUX is given in combination with FOLFIRI (irinotecan, fluorouracil, leucovorin) for patients who are being treated for this type of cancer for the first time.
- ERBITUX is not approved to treat colorectal cancer in patients whose tumors have mutations in genes called *RAS* (often called "*RAS* mutant"), or in patients for whom the mutational status of the genes is not known.

ERBITUX is available by prescription only.

IMPORTANT SAFETY INFORMATION FOR ERBITUX® (cetuximab)

What is the most important information I should know about ERBITUX?

WARNING: ALLERGIC REACTIONS

ERBITUX can cause serious and sometimes fatal allergic reactions. Serious allergic reactions due to ERBITUX therapy occurred in 2.2% of patients receiving ERBITUX during clinical studies; 1 patient died. The risk of anaphylactic reactions may be increased in patients with a history of tick bites, red meat allergy, or in the presence of certain antibodies which can react to ERBITUX.

- **Symptoms can include trouble with breathing (including tightening of the airways, wheezing, or hoarseness), low blood pressure, shock, loss of consciousness, and/or heart attack. Report these signs and symptoms of infusion reactions, as well as fever, and/or chills to your doctor or nurse.**
- **Approximately 90% of the severe allergic reactions occurred with the first treatment with ERBITUX (even if the patient had been premedicated with antihistamines), although some patients experienced their first severe allergic reaction during a later treatment.**
- **Your doctor or nurse should watch you closely for these symptoms during treatment and for at least 1 hour following treatment and may need to stop therapy in the event of an allergic reaction. After the allergic reaction resolves, your doctor may be able to restart therapy.**
- **If you have a severe allergic reaction, treatment with ERBITUX must be stopped immediately and not started again.**

Please see full Prescribing Information for ERBITUX, including Boxed Warnings for allergic reactions.

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ERBITUX® CETUXIMAB
INJECTION FOR INTRAVENOUS INFUSION
100 MG/50 ML & 200 MG/100 ML VIALS

- ERBITUX can cause lung disease. Lung disease occurred in less than 0.5% of 1570 patients receiving ERBITUX in clinical trials for colorectal cancer and head and neck cancer; 1 patient died.
  - o Notify your doctor if you develop shortness of breath, a new or worsening cough and/or chest pain while receiving ERBITUX.
  - o ERBITUX treatment should be stopped if breathing symptoms worsen, and should not be restarted if lung disease is diagnosed.
- ERBITUX can cause skin problems including an acne-like rash, skin drying and cracking, infections (including infections of the blood, skin, eyes, and lips), swelling of the base of the nails or loss of the nails, inflammation of the eye or eyelid, decreased vision, and abnormal hair growth. These symptoms were seen in several clinical trials for colorectal cancer and head and neck cancer with ERBITUX.
  - o Sun exposure may worsen these effects. Patients taking ERBITUX should wear sunscreen and hats to limit sun exposure during treatment and for 2 months after the last dose of ERBITUX.
  - o Severe reactions with symptoms of rash; blistering of the skin, mouth, eyes, and genitals; and shedding of the skin have been seen in patients treated with ERBITUX. These reactions may be life-threatening and possibly lead to death. It is not clear if these reactions are related to the way ERBITUX works or to an immune response, such as Stevens-Johnson syndrome or toxic epidermal necrolysis. Your doctor may withhold, reduce dose, or discontinue ERBITUX based on the severity of these symptoms.
  - o Notify your doctor if you develop any of these symptoms while receiving ERBITUX.
- ERBITUX when given by itself and in combination with other cancer drugs can cause low levels of magnesium, calcium, and potassium.
  - o Your doctor or nurse should periodically monitor your blood electrolyte levels during and for at least 8 weeks after treatment with ERBITUX, and administer intravenous replacement as needed.
- If you have colorectal cancer with mutations in the Ras genes, you should not be treated with ERBITUX because you will not benefit from ERBITUX treatment and will experience side effects.
- ERBITUX can harm your unborn baby. If you are able to become pregnant, you should use effective contraception during treatment with ERBITUX and for 2 months after the last dose of ERBITUX.

What are the most common side effects of ERBITUX?

- The most common side effects (all grades of severity) in patients with Epidermal Growth Factor Receptor (EGFR) positive, KRAS wild-type colorectal cancer that has spread to other parts of the body who were treated with the **European version of ERBITUX in combination with FOLFIRI (irinotecan, fluorouracil, leucovorin) versus FOLFIRI alone** (incidence ≥25%) were: abnormal decrease in certain white blood cell counts, diarrhea, sore mouth, fever, anorexia, a psychological disorder characterized by a loss of appetite and rash which includes a rash including acne-like rash. Most common serious side effects (incidence ≥10%) reported by patients in either arm were: abnormal decrease in certain white blood cell counts, acne-like rash, and diarrhea. ERBITUX results in approximately 22% higher blood levels of cetuximab as compared to the European version of ERBITUX. In this study, the type and severity of side effects seen with European cetuximab were similar to other studies of U.S. patients receiving ERBITUX for metastatic colorectal cancer.
- The most common side effects (all grades of severity) in patients with Epidermal Growth Factor Receptor (EGFR) positive, KRAS wild-type colorectal cancer that has spread to other parts of the body who were treated with **ERBITUX and supportive care versus supportive care alone** (incidence ≥25%) were: rash including shedding of the outer layer of the skin, dry skin, itchy skin, other skin problems, nail changes, feeling tired, fever, other pain, headache, shortness of breath, cough, nausea, constipation, diarrhea, vomiting, sore mouth, infection without decrease in certain white blood cell counts, sensory neuropathy (weakness, numbness, and pain from nerve damage usually in the hands and feet), and problems sleeping. Most common serious side effects (incidence ≥10%) reported by patients included: feeling tired, other pain, rash including shedding of the outer layer of the skin, shortness of breath, other intestinal problems and infection without abnormal decrease in certain white blood cell counts.
- The most common side effects (all grades of severity) in patients with colorectal cancer that has spread to other parts of the body whose tumors had a protein called Epidermal Growth Factor Receptor (EGFR) treated with **ERBITUX and irinotecan** were: acne-like rash, feeling weakness or discomfort, diarrhea, and nausea. The most common serious side effects reported included: diarrhea, decrease in white blood cell count, feeling weakness or discomfort, and acne-like rash.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

What should I tell my doctor before starting treatment with ERBITUX?

Before you start treatment with ERBITUX, tell your doctor:

- If you have a history of breathing problems or other lung problems.
- If you are pregnant or if you plan on becoming pregnant. Because ERBITUX can harm an unborn baby, you should use contraception and not become pregnant during treatment with ERBITUX and for at least 2 months after your last dose of ERBITUX. If you become pregnant during your treatment or within 2 months after your last dose, discuss this with your doctor.
- If you are breastfeeding or plan to breastfeed. ERBITUX may be passed through human breast milk. Because of the potential for serious side effects in nursing infants from ERBITUX, you should not breastfeed during ERBITUX therapy and for 2 months after the last dose of ERBITUX.

Tell your doctor about all the medications you are taking, including prescription and over-the-counter medications.

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