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?

- How do these treatments work? Why are you considering them for me?
- What are the potential long-term and short-term side effects?

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?

INDICATIONS

Head and neck cancer

ERBITUX® is approved:

- In combination with radiation therapy for the initial treatment of a certain type of locally or regionally advanced head and neck cancer
- In combination with platinum-based chemotherapy and fluorouracil for the initial treatment of patients with a certain type of head and neck cancer whose tumor has returned in the same location or spread to other parts of the body
- For use alone to treat patients with a certain type of head and neck cancer whose tumor has returned in the same location or spread to other parts of the body and whose disease has progressed following platinum-based chemotherapy

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 AND HEART ATTACK

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.**

ERBITUX can cause heart attack or sudden death.

- **Heart attack or sudden death occurred in 2% of 208 patients with head and neck cancer treated with radiation therapy and ERBITUX in a clinical study. Three patients with a prior history of coronary artery disease died within six weeks after receiving the last dose of ERBITUX. One patient with no prior history of coronary artery disease died one day after the last dose of ERBITUX.**
- **Heart problems resulting in death or sudden death occurred in 3% of 219 patients with head and neck cancer treated with ERBITUX and platinum-based chemotherapy with fluorouracil in a clinical study.**
- **Notify your doctor if you have a history of any heart disease.**

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

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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.
- Risks when using ERBITUX with radiation and cisplatin. In a study of 940 patients with head and neck cancer, patients received either a combination of radiation and cisplatin (a cancer drug), or ERBITUX in combination with radiation and cisplatin. Adding ERBITUX resulted in an increase in occurrence of severe or life-threatening redness and sores of the lining of the mouth, lips, or throat and other digestive organs; skin reactions caused by certain cancer drugs given after radiation; acne-like rash; heart problems; and blood electrolyte disturbances (compared to radiation and cisplatin alone).
  - o Side effects resulting in death occurred in 4% of patients in the ERBITUX plus radiation and cisplatin treatment arm, and 3% in the radiation therapy and cisplatin alone treatment arm.
  - o 2% of patients in the ERBITUX plus radiation and cisplatin treatment arm experienced decreased blood flow to the heart, compared to 0.9% in the radiation therapy and cisplatin alone treatment arm.
  - o The main point of the study was to measure how long patients survived before their cancer got worse. Adding ERBITUX to radiation and cisplatin did not improve this measure.
- 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.
- 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) reported in patients with head and neck cancer treated with **ERBITUX in combination with radiation therapy versus radiation therapy alone** (incidence ≥25%) were: feeling weak, fever, nausea, vomiting, weight loss, dehydration, elevated liver enzymes in blood tests, sore throat, acne-like rash, and skin irritation in the radiation area. In areas treated with radiation therapy, the addition of ERBITUX to the radiation therapy increases the risk of damage to surrounding healthy tissues in the area treated with radiation. The most common serious side effects (incidence ≥10%) reported by patients included skin irritation in the radiation area, acne-like rash, and weight loss.
- The most common side effects (all grades of severity) in patients with head and neck cancer treated with the **European version of ERBITUX in combination with platinum-based chemotherapy with fluorouracil versus chemotherapy alone** (incidence ≥25%) were: acne-like rash, nausea, infection, rash, diarrhea, and anorexia, a psychological disorder characterized by a loss of appetite. Most common serious side effects (incidence ≥10%) reported by patients in either arm was: infection. ERBITUX results in approximately 22% higher blood levels of cetuximab as compared to the European version of ERBITUX. It is possible that U.S. patients receiving ERBITUX may experience more frequent or severe side effects than patients in the study conducted in Europe.

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 any history of heart disease or a heart condition.
- 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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