Cetuximab (s-e-tux-i-mab)

**Indications**
Locally or regionally advanced squamous cell carcinoma of the head and neck with radiation. Recurrent or metastatic squamous cell carcinoma of the head and neck in combination with platinum-based therapy with 5-fluorouracil. K-ras mutation-negative (wild-type), epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer in patients who have not responded to irinotecan and oxaliplatin or are intolerant to irinotecan.

**Action**
Binds specifically to EGFR, thereby preventing the binding of endogenous epidermal growth factor (EGF). This prevents cell growth and differentiation processes. Combination with irinotecan enhances antitumor effects of irinotecan.

**Therapeutic Effects:**
Decreased tumor growth and spread.

**Pharmacokinetics**
**Absorption:** IV administration results in complete bioavailability.
**Distribution:** Unknown.
**Metabolism and Excretion:** Unknown.
**Half-life:** 97–114 hr.

**Contraindications/Precautions**
Contraindicated in: Hypersensitivity to cetuximab or murine (mouse) proteins; K-Ras mutation-positive colorectal cancer; Patients with colorectal cancer whose tumors have RAS mutations in codons 12 or 13 (not effective); GI, Gastrointestinal: Patients with colorectal cancer whose tumors have K-Ras mutations in codons 12 or 13 (not effective); Use Cautiously in: Exposure to sunlight (may exacerbate dermatologic toxicity); Pedi: Safety not established.

**Adverse Reactions/Side Effects**
Most adverse reactions reflect combination therapy with irinotecan.

**CNS:** malaise, depression, headache, insomnia.

**EENT:** conjunctivitis, ulcerative keratitis.

**Resp:** cough, dyspnea, interstitial lung disease.

**CV:** cardiopulmonary arrest, pulmonary embolism, sudden cardiac death.

**GI:** abdominal pain, constipation, diarrhea, nausea, vomiting, anorexia, stomatitis.

**GU:** renal failure.

**Derm:** acneform dermatitis, hypertrichosis, nail disorder, pruritus, skin desquamation, skin infection.

**F and E:** dehydration, hypomagnesemia, peripheral edema.

**Hemat:** anemia, leukopenia.

**MS:** back pain.

**Metab:** weight loss.

**Misc:** infusion reactions, fever, desquamation of mucosal epithelium.

**Interactions**
**Drug-Drug:** None noted.

**Route/Dosage**

**Head & Neck Cancer with Radiation or in Combination with Platinum-Based Therapy with 5-Fluorouracil**

**IV (Adults):**
- Administer 400 mg/m² administered 1 wk prior to initiation of radiation therapy or on the day of initiation of platinum-based therapy with 5-fluorouracil (complete infusion 1 hr prior to starting platinum-based therapy with 5-fluorouracil), followed by weekly maintenance doses of 250 mg/m² for the duration of radiation therapy or until disease progression or unacceptable toxicity with platinum-based therapy with 5-fluorouracil (complete infusion 1 hr prior to radiation therapy or platinum-based therapy with 5-fluorouracil). Dose modification recommended for dermatologic toxicity.

**TIME/ACTION PROFILE**

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Head and Neck Cancer Monotherapy
IV (Adults): 400 mg/m² initial loading dose, followed by weekly maintenance doses of 250 mg/m² until disease progression or unacceptable toxicity; dose modification recommended for dermatologic toxicity.

Colorectal Cancer
IV (Adults): 400 mg/m² initial loading dose, followed by weekly maintenance doses of 250 mg/m² until disease progression or unacceptable toxicity; dose modification recommended for dermatologic toxicity.

NURSING IMPLICATIONS
Assessment
- Assess for infusion reaction (rapid onset of airway obstruction [bronchospasm, stridor, hoarseness], urticaria, hypotension, loss of consciousness, myocardial infarction, cardiopulmonary arrest) for at least 1 hr following infusion. Longer observation periods may be required for those who experience infusion reactions. Most reactions occur during first dose, but may also occur in later doses. For severe reactions, immediately stop infusion and discontinue cetuximab permanently. Epinephrine, corticosteroids, IV antihistamines, bronchodilators, and oxygen should be available for reactions.
- Assess for onset or worsening of pulmonary symptoms. Interrupt therapy to determine nature of symptoms. If interstitial lung disease is confirmed, discontinue cetuximab and treat appropriately.
- Assess for dermatologic toxicities (acneform rash, skin drying and fissuring, inflammatory and infectious sequelae [blepharitis, cheilitis, cellulitis, cyst]). Treat symptomatically. Acneform rash usually occurs within initial 2 wk of therapy and resolves following cessation, but may continue up to 28 days following therapy.
- Lab Test Considerations: Determine K-Ras mutation and EGFR-expression status using FDA-approved tests prior to initiating treatment. Only patients whose tumors are K-Ras mutation-negative (wild-type) should receive cetuximab.
- Lab Test Considerations: May cause anemia and leukopenia.
- Monitor serum electrolytes, especially serum magnesium, potassium, and calcium, closely during and periodically for at least 8 wk following infusion. May cause hypomagnesemia, hypocalcemia, and hypokalemia; may occur from days to months after initiation of therapy. May require electrolyte replacement. May lead to cardiopulmonary arrest and sudden death.

Potential Nursing Diagnoses
Ineffective breathing pattern (Adverse Reactions)
Impaired skin integrity (Adverse Reactions)

Implementation
- Premedicate with histamine 1 antagonist (diphenhydramine 50 mg) 30–60 min prior to first dose. Have subsequent administration on presence and severity of infusion reaction.
- Administer through a low protein binding 0.22-micrometer in-line filter placed as proximal to patient as possible. Solution should be clear and colorless and may contain a small amount of white amorphous protein particles. Do not shake or dilute.
- Can be administered via infusion pump or syringe pump. Cetuximab should be piggybacked to the patient’s infusion line.
- Accelerate for 1 hr following infusion.

IV Administration
- pH: 7.0–7.4.
- Intermittent Infusion: For administration via infusion pump. Draw up volume of a vial using sterile needle or other transfer device. Transfer to a sterile, evacuated container or bag. Repeat with new needle for each vial until calculated volume is in container. Affix infusion line and prime with cetuximab before starting infusion.
- For administration via syringe pump. Draw up volume of a vial using sterile needle attached to an appropriate tubing set. Place tubing into venting device of a syringe pump and set rate. Connect infusion line and prime with cetuximab. Do not use with membrane filters.
- Concentration: 2 mg/mL. Rate: Administer over 2 hr at a rate not to exceed 10 mg/min. Use 0.9% NaCl in D5W at end of infusion.
- Cetuximab infusion must be completed 1 hr prior to FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) regimen. May infuse subsequent weekly infusions over 1 hr.

Patient/Family Teaching
- Explain purpose of cetuximab and potential side effects to patient.
- Advise patient to report dermatologic changes and signs and symptoms of infusion reactions (fever, chills, or breathing problems) promptly.

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**CONTINUED**

**cetuximab**

- Caution patient to wear sunscreen and hats and limit sun exposure during therapy during and for 2 mos following last dose of cetuximab.
- Advise both female and male patients to use adequate contraception during and for 6 mos following therapy and to avoid breast feeding during and for 2 mos following therapy.

**Evaluation/Desired Outcomes**

- Decreased tumor growth and spread.

Why was this drug prescribed for your patient?