



Cetuximab Injection

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IMPORTANT WARNING:

Cetuximab may cause severe or life-threatening reactions while you receive the medication. These reactions are more common with the first dose of cetuximab, but may occur at any time during treatment. Your doctor will watch you carefully while you receive each dose of cetuximab and for at least one hour afterwards. Tell your doctor if you experience any of the following symptoms during or after your infusion: shortness of breath, wheezing or noisy breathing, hoarseness, hives, fainting, dizziness, blurred vision, nausea, or chest pain or pressure. If you experience a severe reaction, your doctor will stop your infusion and treat the symptoms of the reaction. You will not be able to receive treatment with cetuximab in the future.

People with a head and neck cancer who are treated with radiation therapy and cetuximab may have an increased risk of cardiopulmonary arrest (condition in which the heart stops beating and breathing stops) and/or sudden death during or after their treatment. Tell your doctor if you have or have ever had coronary artery disease (condition that occurs when the blood vessels of the heart are narrowed by fat or cholesterol deposits); angina (chest pain or pressure); a heart attack; congestive heart failure; irregular heartbeat; other heart disease; or lower than normal levels of magnesium, potassium, or calcium in your blood.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests during and after your treatment to check your body's response to cetuximab.

Talk to your doctor about the risks of using cetuximab.

Why is this medication prescribed?

Cetuximab is used with or without radiation therapy to treat a certain type of cancer of the head and neck. Cetuximab is also used alone or in combination with another medication to treat a certain type of cancer of the colon (large intestine) or rectum that has spread to other parts of the body. Cetuximab has been shown to slow the growth of tumors in people who have cancer of the colon or rectum. However, it has not been shown to help people who have cancer of the colon or rectum feel better or live longer. Cetuximab is in a class of medications called monoclonal antibodies. It works by slowing or stopping the growth of cancer cells.

How should this medicine be used?

Cetuximab comes as a solution (liquid) to be infused (injected slowly) into a vein. Cetuximab is given by a doctor or nurse in a medical office or infusion center. It is usually given once a week.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving treatment with cetuximab,

- tell your doctor and pharmacist if you are allergic to cetuximab, any medications that are made from murine (mouse) proteins, or any other medications. Ask your doctor or pharmacist if you don't know whether a medication that you are allergic to is made from murine proteins.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention if you are receiving treatment with cisplatin (Platinol). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had lung disease.
- tell your doctor if you are pregnant or plan to become pregnant. Use effective birth control to prevent pregnancy during your treatment with cetuximab. If you become pregnant while using cetuximab, call your doctor.
- tell your doctor if you are breast-feeding. You should not breastfeed during your treatment with cetuximab or for 60 days after you stop using the medication.
- plan to avoid unnecessary or prolonged exposure to sunlight and to wear protective clothing, a hat, sunglasses, and sunscreen. Cetuximab may make your skin sensitive to sunlight.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss an appointment to receive a dose of cetuximab, call your doctor right away.

What side effects can this medication cause?

Cetuximab may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- acne-like rash
- dry or cracking skin
- swelling or pain in the fingernails or toenails
- red, watery, or itchy eye(s)
- red or swollen eyelid(s)
- pain or burning sensation in eye(s)
- sensitivity of eyes to light
- hair loss
- dry mouth
- chapped lips

- mouth sores
- difficulty swallowing
- headache
- tiredness
- weakness
- difficulty falling asleep or staying asleep
- depression
- nausea
- vomiting
- constipation
- stomach pain
- heartburn
- loss of appetite
- weight loss
- pain, especially in the back
- pain, redness, or swelling at injection spot

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- swelling of the hands, feet, ankles, or lower legs
- fast heartbeat
- coughing up blood or dry cough
- shortness of breath or unusual tiredness during exercise
- fainting
- decreased urination
- muscle cramps
- shaking of the hands that you cannot control
- sudden tightening of the hands or feet
- twitching of the body that you cannot control
- sore throat, fever, chills, and other signs of infection
- diarrhea
- confusion
- itching
- hives
- red, swollen, or infected skin

Cetuximab may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online [at <http://www.fda.gov/MedWatch/index.html>] or by phone [1-800-332-1088].

In case of emergency/overdose

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

What other information should I know?

Ask your doctor if you have any questions about your treatment with cetuximab.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Erbitux®

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