ERBITUX, in combination with radiation therapy, is approved for the initial treatment of a certain type of locally or regionally advanced head and neck cancer.

ERBITUX, in combination with platinum-based chemotherapy with 5-fluorouracil, is approved 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.

ERBITUX is also approved 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.

**WARNING: ALLERGIC REACTIONS and HEART ATTACK**

**Allergic Reactions**

- Severe allergic reactions due to ERBITUX® (cetuximab) therapy have occurred in 42 of 1373 patients (3%) receiving ERBITUX during clinical studies, resulting in death in less than 1 in 1000 patients.
  - 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, chills, or breathing problems to your doctor or nurse.
  - Approximately 90% of the severe allergic reactions occurred with the first dose of ERBITUX, although some patients experienced their first severe allergic reaction during a subsequent dose of ERBITUX.
  - Your doctor or nurse should watch you closely for these symptoms during treatment and may need to stop therapy in the event of an allergic reaction.
  - Severe allergic reactions require that treatment with ERBITUX be stopped immediately and not started again.

**Heart Attack**

- Heart attack and/or sudden death occurred in 4 of 208 patients (2%) with head and neck cancer treated with radiation therapy and ERBITUX, as compared to none of 212 patients treated with radiation therapy alone.
- Heart problems resulting in death and/or sudden death occurred in 7 of 219 patients (3%) with head and neck cancer treated with platinum-based chemotherapy with 5-fluorouracil and cetuximab compared to 4 of 215 patients (2%) treated with chemotherapy alone, based on a study conducted in Europe using European cetuximab.
- 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.
This brochure, along with advice from your doctor, will help guide you and your loved ones through your treatment journey. Inside, you will find ways to:

- Learn about your diagnosis
- Understand your treatment better
- Learn about financial assistance options through Lilly PatientOne
- Care for certain side effects associated with ERBITUX treatment
- Learn about a complimentary self-care kit with information and products that may help with skin care

4 What is head and neck cancer?
6 What happens after diagnosis?
8 How was ERBITUX shown to work?
9 How will I be given ERBITUX?
10 ERBITUX side effects
12 Tips to care for select side effects
14 Caring for your skin, nails, and hair during treatment
15 Learn about financial assistance options through Lilly PatientOne
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18 Important Safety Information
21 Glossary of common terms

This brochure can’t replace information or advice given by your doctor or nurse. Your healthcare team will tell you more about your condition and treatment plan and answer any questions you may have.

Please see full Prescribing Information for ERBITUX, including Boxed Warnings for allergic reactions and heart attack.
Metastatic cancer
Cancer that has spread from the place where it started to other places in the body. No matter where a cancer may spread, it's always named for the place where it started. For example, head and neck cancer that has spread to the lung is called metastatic head and neck cancer, not lung cancer. Head and neck cancer most commonly spreads to the lung, followed by bone and liver.

**Squamous cell carcinoma**
Cancer that begins in thin, flat cells that make up the lining of many areas of the body, including many parts of the head and neck.

**Lymph node**
Lymph nodes filter lymph (lymphatic fluid), and they store lymphocytes (white blood cells).

**Lung metastasis**
Cancer that has spread from the place where it started to other places in the body.

**Metastatic**
The cancer has spread from the place where it started to other places in the body.

For more definitions, please see page 21.

**Head and neck cancer**
Refers to a group of different cancers that develop in the nose, mouth, and throat. The most common form of head and neck cancer is called squamous cell carcinoma, which grows from the mucous cells lining the inside of the nose, mouth, and throat.

**Stages of head and neck cancer**

- **Locally or regionally advanced cancer**
  Cancer that has spread from where it started to nearby tissue or lymph nodes.

- **Metastatic cancer**
  Cancer that has spread from the place where it started to other places in the body.

**Recurrent cancer**
Cancer that has come back, usually after a period of time during which the cancer could not be detected.

**SELECT IMPORTANT SAFETY INFORMATION**

**Lung Disease**
- Lung disease, which resulted in one death, occurred in 4 of 1570 patients (<0.5%) receiving ERBITUX in several clinical trials in colorectal cancer and head and neck cancer
  - Notify your doctor if you develop shortness of breath while receiving ERBITUX
  - ERBITUX treatment should be stopped if symptoms worsen or lung disease is confirmed

Please see full Prescribing Information for ERBITUX, including Boxed Warnings for allergic reactions and heart attack.
After your diagnosis, you and your doctor will work together to decide what the best treatment is for you. This decision will be based on a number of factors, including the size and location of the tumor, whether the tumor has spread to other areas of the body, and your general health and preferences.

**Some Common treatment options for head and neck cancer**

**Surgery**
A procedure or operation to remove or repair a part of the body or to find out whether disease is present.

**Radiation therapy (also called radiotherapy)**
Treatment of disease using high-energy waves or streams of particles called radiation.

**Chemotherapy**
A certain group of drugs used to treat patients with cancer.

**Biologic therapy**
A substance that is made from a living organism or its products used in the prevention, diagnosis, or treatment of cancer and other diseases. Biologic agents include antibodies, interleukins, and vaccines.

In some cases, treatments may be combined.

**Assessing treatment with your healthcare team**
Typically, 6-8 weeks after you start treatment, your doctor may do a CT, PET, or other kind of scan to see whether or not the treatment is working. A scan after treatment enables your doctor to tell you if your tumor disappeared, shrunk, stayed the same, or grew. You may continue to have scans taken during and after treatment.

**Your healthcare team**
The treatment of head and neck cancer will differ from patient to patient, but it often requires the use of a team of doctors and specialists. Your healthcare team may include:

- Dentist
- Radiologist
- Medical Oncologist
- Radiation Oncologist
- Oncology Nurse
- Oral Surgeon

**Other specialists you may see during your treatment**
- Dietitian
- Oral pathologist
- Prosthodontist
- Plastic surgeon
- Head and neck surgeon
- Ear, nose, and throat doctor
- Physical therapist
- Speech pathologist

**Computed tomography (CT) scan**
Also called a CAT scan, which is a series of detailed pictures of areas inside the body created by a computer linked to an X-ray machine.

**Positron emission tomography (PET) scan**
A procedure in which a small amount of radioactive sugar is injected into a vein, and a scanner is used to make pictures of areas inside the body where the sugar can be found. Cancer cells often take up more sugar than normal cells, so a PET scan can be used to find cancer cells in the body.

For more definitions, please see page 21.

Please see full Prescribing Information for ERBITUX, including Boxed Warnings for allergic reactions and heart attack.
How was ERBITUX shown to work?

In laboratory studies, ERBITUX was shown to:

Block the signal

ERBITUX can block one of the signals that tells a tumor cell to grow by attaching to a structure on the cell called the epidermal growth factor receptor (EGFR). This structure is found on both normal cells and tumor cells.

Trigger an immune response

ERBITUX can form a bridge between a tumor cell and an immune cell when it is attached to the EGFR on the tumor cell. As a result, the immune cell can begin a response against the tumor cell.

EGFR

- EGFR is a receptor that is important for cell growth
- EGFR is present on some cancer cells, including head and neck cancer
- EGFR is also present on normal cells like skin, nail, or hair follicles

Laboratory studies have shown that ERBITUX does not have an effect against tumor samples that do not have EGFR.

If you experience a side effect, your ERBITUX treatment may need to be changed, delayed, or stopped completely.

WARNING: ALLERGIC REACTIONS

Allergic Reactions

- Severe allergic reactions due to ERBITUX® (cetuximab) therapy have occurred in 42 of 1373 patients (3%) receiving ERBITUX during clinical studies, resulting in death in less than 1 in 1000 patients
  - 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, chills, or breathing problems to your doctor or nurse
  - Approximately 90% of the severe allergic reactions occurred with the first dose of ERBITUX, although some patients experienced their first severe allergic reaction during a subsequent dose of ERBITUX
  - Your doctor or nurse should watch you closely for these symptoms during treatment and may need to stop therapy in the event of an allergic reaction
  - Severe allergic reactions require that treatment with ERBITUX be stopped immediately and not started again

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.
ERBITUX may cause side effects. Some can be serious and sometimes fatal, so it is very important that you notify your doctor immediately if you develop any symptoms while receiving ERBITUX. If you experience a side effect, your ERBITUX treatment may need to be changed, delayed, or stopped completely.

Select side effects

Allergic reactions
Severe allergic reactions are a serious side effect with ERBITUX. Allergic reactions are rare but may cause death. Tell your doctor or nurse right away if you have trouble breathing, are wheezing or hoarse, or have fever, chills, or a tight feeling in your airways. Symptoms can also include low blood pressure, shock, loss of consciousness, and/or heart attack. Severe allergic reactions can happen at any time during treatment, but they happen most often at the first dose.

Heart attack
Heart attack is a serious side effect with ERBITUX. Heart attack and/or sudden death has occurred in some people who received ERBITUX and radiation therapy or cetuximab with platinum-based chemotherapy with 5-fluorouracil. Tell your doctor if you have a history of heart disease.

Skin problems
Skin problems are one of the most serious side effects of ERBITUX. Skin problems include an acne-like rash, skin drying and cracking, infections, and abnormal hair growth. The skin around your fingernails and toenails may swell. Blistering of the skin or mucous membranes (such as the mouth) or peeling of the skin may be symptoms of serious reactions that could lead to death. Contact your doctor right away if you have any of these symptoms.

ERBITUX side effects

Platinum agents
Anticancer medicines that are made from the metal platinum.

5-fluorouracil
A drug used to treat certain cancers. Also called 5-FU.

For more definitions, please see page 21.

ERBITUX may cause nail changes.
Nail changes during EGFR treatment may:
- Look like pus-filled blisters or swollen, red skin around the fingernails or toenails
- Cause ingrown nails or infection
- Cause nails to form ridges or to fall off
- Be swollen and painful
- Appear 2 to 4 months after starting treatment
- Last for many months after treatment

ERBITUX may cause hair changes.
Hair changes during EGFR treatment may:
- Make the eyelashes grow very fast and become very long and bother your eyes
- Cause fast growth to eyebrows
- Cause hair on the scalp to become curly, fine, or brittle
- Start a few weeks to months after starting treatment and go away after treatment is stopped

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.

Picture of swollen, discolored fingernail.
This image is an example only.

Picture of fast-growing eyelashes.
This image is an example only.

Side effects for each person may vary. Tell your doctor or nurse if you notice any skin, nail, or hair changes, or any other side effects.

ERBITUX may cause an acne-like skin rash.
An acne-like skin rash during EGFR treatment may:
- Look like acne, but it is not
- Be red, swollen, crusty, and very dry
- Feel itchy, tender, painful, or warm or burning (like a sunburn)
- Happen on the scalp, face, chest, or upper back, or other parts of the body if the case is severe
- Start and may be worse during the first few weeks of treatment
- Get better or stay the same during treatment
- Go away after treatment is stopped, but not always immediately
- Become infected
- Cause the skin to change color after the rash has gone away

Picture of skin rash on the face.
This image is an example only.
Tips to care for select side effects

Tips to help care for skin problems

What to do
- Talk to your doctor or nurse about management of skin problems
- Your doctor or nurse may suggest the use of moisturizing lotion to help keep skin moist
- They may also suggest cool compresses to relieve itching
- Being out in the sun may make skin problems worse. People receiving ERBITUX should wear sunscreen and hats and limit sun exposure during treatment and for 2 months following the last dose of ERBITUX
- Rash may be treated with antibiotics. Antibiotics may be in pill form (and may be taken by mouth) or as a skin cream

Tips to help care for diarrhea

What to do
- Tell your doctor if you experience diarrhea
- Eat many small meals, rather than 3 normal-size meals
- Eat Bananas, white Rice, Applesauce, white Toast (the BRAT diet)
- Drink plenty of water, clear liquids, or sports drinks

What to avoid
- Do not drink milk or eat milk products, such as ice cream
- Do not eat greasy or spicy foods
- Avoid whole wheat or whole grain foods and other foods high in fiber, such as raw vegetables, beans, and nuts

Tips to help care for fatigue and/or weakness

What to do
- Tell your doctor if you have fatigue or weakness
- Make a plan for each day that includes time for activity and time for rest. Try to do the most important things first, while you have energy
- Keep a journal of how you feel each day, noting when you are tired or feeling energetic
- Do small amounts of activity to give yourself energy
- For persistent fatigue, talk to your doctor

What to avoid
- Avoid foods or drinks with caffeine, such as coffee or chocolate, in the afternoon or night
- If you are having trouble sleeping at night, avoid late-afternoon naps

Tips to help care for nausea

What to do
- Tell your doctor if you have nausea
- Eat smaller meals more often during the day
- Eat foods that are light or bland (have a mild flavor), such as chicken noodle soup or scrambled eggs
- Eat dry foods, such as crackers, bread, or dry cereal, when you first wake up or if your stomach is empty
- Sip clear liquids, such as water or a sports drink, or suck on ice chips or ice pops
- Rest a bit after eating, but avoid lying down flat for at least 1 hour after a meal
- Rinse your mouth before and after you eat a meal

You may experience other side effects while being treated with ERBITUX. Your treatment team is there to help, so be sure to let them know about any side effects that are bothering you.

Please see full Prescribing Information for ERBITUX, including Boxed Warnings for allergic reactions and heart attack.
Caring for your skin, nails, and hair during treatment

Get your complimentary self-care kit
The self-care kit contains information on the possible side effects of EGFR inhibitors, such as ERBITUX, as well as products and suggestions to help with skin care. Using the tips and materials in the self-care kit may help manage side effects. If you have any questions, please be sure to discuss them with your treatment team. Talk to your doctor to determine if the self-care kit is right for you.

The self-care kit includes

Advice
- A brochure with information about potential skin, nail, and hair changes
- Helpful tips

Care products
- Lotions
- Sunscreen
- Gentle bathing products
- Nail care kit

Ask your doctor or visit ERBITUX.com for more information about the self-care kit.

Lilly PatientOne may help with the costs of your prescribed Lilly Oncology medications
Find easy-to-use forms and reimbursement information to help support your patient’s treatment journey.
Lilly PatientOne is committed to helping eligible patients access support programs for Lilly Oncology products they are prescribed. We aim to address both financial and coverage issues for qualified uninsured, underinsured, and insured patients. Lilly PatientOne strives to offer resources, ranging from benefits investigations to financial assistance and appeals information, that provide reliable and individualized treatment support for eligible patients.

For more information about Lilly PatientOne, call 1-866-4PatOne (1-866-472-8663), Monday–Friday, 9 AM–7 PM ET, or visit LillyPatientOne.com.

Please see full Prescribing Information for ERBITUX, including Boxed Warnings for allergic reactions and heart attack.
What does it mean to be a caregiver?

After cancer is diagnosed, the person you love will face a challenging journey. As a caregiver, you will share that journey and become a source of comfort and support. As a caregiver, you are going to help your loved one with everyday tasks. These can include:

- Preparing food
- Helping with things around the house
- Taking them to the doctor

Your most important role as a caregiver is providing emotional and spiritual support for your loved one. It is also important to be there to help them cope with their cancer and provide support through their treatment.

As a caregiver, it’s important to take care of yourself, too

While caring for your loved one, you may feel as if you don’t have time to take care of yourself. After a while your emotional and physical well-being may suffer. Taking care of yourself will help you take better care of your loved one. Make time for yourself every day.

10 ways to help care for yourself

- Find comfort in things you enjoy doing
- Look for positives to bring your spirits up
- Find acceptance and vow to live each day to its fullest
- Feel thankful that you can be there for your loved one
- Connect with other people so you won’t get overwhelmed
- Let yourself laugh to release tension
- Write in a journal to relieve negative thoughts
- Confront your anger and try to defuse it the moment it happens
- Let go of your guilt to help you focus on what you need to do
- Join a support group so you know you’re not alone

Tips to help maintain your health

- Eating well will help you keep up your strength
- Get plenty of rest to stay energized during the day
- Exercise is a great way to keep your body healthy and mind clear
- Learn how to relax to help relieve stress

You can get support

You’re not alone, but sometimes when looking after your loved one it may feel that way. This can cause increased levels of stress, feelings of being overwhelmed, and even physical sickness. Remember, there is nothing wrong with asking for help.

To find support, contact:
Caregiver Action Network
1-301-942-6430
www.caregiveraction.org

If the responsibility of caring for your loved one is causing you to experience signs of fatigue, weight loss or weight gain, changes in appetite, headaches, or mood swings, be sure to speak with your physician.
Please see full Prescribing Information for ERBITUX, including Boxed Warnings for allergic reactions and heart attack.
IMPORTANT SAFETY INFORMATION (CONTINUED)

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. 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 5-fluorouracil versus chemotherapy alone (incidence ≥25%) were: acne-like rash, nausea, infection, rash, diarrhea and 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.

ERBITUX is available by prescription only.

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

Glossary of common terms

5-fluorouracil: A drug used to treat certain cancers. Also called 5-FU.

Allergic reaction: A reaction that happens when a person comes in contact with a substance to which that person is especially sensitive.

Cell: The individual unit that makes up the tissues of the body.

Computed tomography (CT) scan: Also called a CAT scan, which is a series of detailed pictures of areas inside the body created by a computer linked to an X-ray machine.

Diagnosis: The process of identifying a disease, such as cancer, from its signs and symptoms. A health history, physical exam, and tests may be used to make a diagnosis.

EGFR: EGFR is a receptor found on both normal and tumor cells that is important for cell growth.

Intravenous (IV) infusion: A type of injection in which a medicine is given over time directly into the blood through a vein.

Lymph node: Lymph nodes filter lymph (lymphatic fluid), and they store lymphocytes (white blood cells).

Metastatic: The cancer has spread from the place where it started to other places in the body.

Platinum agents: Anticancer medicines that are made from the metal platinum.

Positron emission tomography (PET) scan: A procedure in which a small amount of radioactive sugar is injected into a vein, and a scanner is used to make pictures of areas inside the body where the sugar is taken up. Cancer cells often take up more sugar than normal cells, so a PET scan can be used to find cancer cells in the body.

Scan: A picture of structures inside the body. Scans often used in diagnosing, staging, and monitoring disease include liver scans, bone scans, computed tomography (CT) or computerized axial tomography (CAT) scans, and magnetic resonance imaging (MRI) scans.

Side effect: A problem that occurs when treatment affects healthy tissues or organs.

Squamous cell carcinoma: Cancer that begins in thin, flat cells that make up the lining of many areas of the body, including many parts of the head and neck.

Tumor: An abnormal mass of tissue that forms when cells grow and divide uncontrollably. A tumor may be either benign (not cancerous) or malignant (cancerous).
Get involved: Educate yourself.

Educating yourself—whether it’s your diagnosis or a loved one’s—is an important step, regardless of whether you’re newly diagnosed or have been living with head and neck cancer for a while. There are many outside resources you can turn to, whether you want to learn more about your cancer or you’re looking for support from other people who are going through the same thing.

Websites you may find helpful

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<tr>
<th>SUPPORT</th>
<th>Support for People With Oral and Head and Neck Cancer (SPOHNC)</th>
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<tr>
<td>Association of Cancer Online Resources®</td>
<td>1-800-377-0928 · <a href="http://www.spohnc.org">www.spohnc.org</a></td>
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<td>CancerCare®</td>
<td>American Cancer Society®</td>
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<td>1-800-813-HOPE (1-800-813-4673)</td>
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<td>Cancer Support Community</td>
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<td>1-888-793-9355</td>
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<td>1-202-454-3970 · <a href="http://www.caregiveraction.org">www.caregiveraction.org</a></td>
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<td>Head and Neck Cancer Alliance</td>
<td>1-800-532-5274 · <a href="http://www.patientadvocate.org">www.patientadvocate.org</a></td>
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<td>1-866-792-HNCA (1-866-792-4622)</td>
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Please see full Prescribing Information for ERBITUX, including Boxed Warnings for allergic reactions and heart attack.