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Erbitux (*cetuximab*)

A plain-language overview of Erbitux and why it is authorised in the EU

What is Erbitux and what is it used for?

Metastatic colorectal cancer

Erbitux is a medicine used to treat metastatic colorectal cancer (cancer of the large bowel or rectum). Metastatic means that the cancer has spread to other parts of the body.

Erbitux is used in patients whose tumour cells have a protein on their surface called epidermal growth factor receptor (EGFR) and contain wild-type (non-mutated) versions of a family of genes called RAS. Erbitux is given in the following ways:

- together with other cancer medicines containing irinotecan;
- together with a combination of cancer medicines containing oxaliplatin, called FOLFOX, in patients who have not been treated before;
- on its own when previous treatment containing oxaliplatin and irinotecan has failed and the patient cannot receive irinotecan.

Erbitux is also used to treat adults with metastatic colorectal cancer when the tumour cells have a genetic mutation called BRAF V600E. In these patients, it is used together with encorafenib, a cancer medicine that blocks the protein BRAF. Erbitux and encorafenib can be used:

- together with FOLFOX in patients who have not been treated before;
- in patients who have previously received systemic therapy (treatment affecting the whole body).

Squamous cell cancer of the head and neck

Erbitux is also used to treat squamous cell cancers of the head and neck. These types of cancer affect the cells of the lining of the mouth or the throat, or of organs such as the larynx (voice box).

In locally advanced cancer (when the tumour has grown but has not spread), Erbitux is given in combination with radiotherapy (treatment with radiation). In cancer that is recurrent (when it has come back after previous treatment) or metastatic, Erbitux is used with a platinum-based cancer medicine combination (including medicines such as cisplatin or carboplatin).

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Erbitux contains the active substance cetuximab.

How is Erbitux used?

Erbitux can only be obtained with a prescription and should be given under the supervision of a doctor experienced in using cancer medicines and in a setting where facilities for resuscitation are available.

It is given either once a week or once every two weeks as an infusion (drip) into a vein over 2 hours. Before receiving Erbitux, the patient must be given an antihistamine and a corticosteroid to prevent an allergic reaction. Patients must also be closely observed for any signs of allergic reaction for at least one hour after the end of the infusion.

When it is used on its own or with other cancer medicines, Erbitux is continued for as long as the patient benefits from it. When it is used with radiotherapy, Erbitux is started one week before the radiotherapy starts and continued until the radiotherapy ends.

For more information about using Erbitux, see the package leaflet or contact your doctor or pharmacist.

How does Erbitux work?

The active substance in Erbitux, cetuximab, is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure in the body. Cetuximab has been designed to attach to EGFR, which can be found on the surface of some cancer cells. EGFR is involved in switching on proteins called RAS that are involved in the growth of cells; by attaching to EGFR, cetuximab prevents this from happening in the cancer cells and helps stop them growing. Most colorectal and squamous cell cancers of the head and neck have EGFR on their cell surfaces.

In colorectal cancer with the BRAF V600E mutation, the cancer cells produce an abnormal form of a protein called BRAF, which is also involved in uncontrolled cell growth that can lead to cancer. These cancers are treated with a medicine that blocks the activity of BRAF (BRAF inhibitor). However, the cells can evade the effect of a BRAF inhibitor by using EGFR to multiply and grow instead. By blocking EGFR activity, cetuximab, used together with a BRAF inhibitor, can block the growth of these cancer cells . Around 1 in 10 colorectal cancers have a BRAF V600E mutation.

What benefits of Erbitux have been shown in studies?

Erbitux has been studied in several main studies in patients with metastatic cancer of the colon or rectum and cancers of the head and neck. The main measures of effectiveness were how long patients lived without their disease getting worse or how long they survived.

Metastatic colorectal cancer

In the studies of cancer of the colon or rectum, Erbitux was shown overall to increase the time patients lived without their cancer getting worse or how long they survived.

Colorectal cancer with wild-type RAS gene

Two studies involved 1,535 patients who had not received chemotherapy before and looked at the effects of adding Erbitux to a treatment combination containing either irinotecan or oxaliplatin (FOLFOX). The studies found that patients who had wild-type KRAS in their tumours lived for longer without their disease getting worse when they received Erbitux in addition to irinotecan chemotherapy (median time of 9.9 months compared with 8.4 months). In patients receiving Erbitux in combination

with FOLFOX, patients with wild-type RAS lived for longer without their disease getting worse compared with patients on FOLFOX alone (median time of 12.0 months compared with 5.8 months).

A third study looked at the effects of adding Erbitux to two treatment combinations containing oxaliplatin (one of which was similar to FOLFOX) in 1,630 patients. In this study, patients with wild-type KRAS only survived overall for a median of 16.3 months when Erbitux was added to an oxaliplatin-based treatment similar to FOLFOX, compared with a median of 18.2 months when the oxaliplatin-based treatment was used alone.

Three other studies involved 2,199 patients whose disease had got worse while they were on previous treatment including irinotecan, oxaliplatin or both, or who could not receive these medicines. The first study did not look at RAS mutations, but in the other two studies, patients with wild-type KRAS in their tumours lived for longer without their disease getting worse when Erbitux was added to their treatment. Patients who had failed both oxaliplatin and irinotecan treatment lived for a median of 3.6 months without their disease getting worse with Erbitux, compared with a median of 1.9 months for those receiving best supportive care alone (the treatment of symptoms but not the cancer itself). Patients who had failed oxaliplatin treatment lived for a median of 4.0 months without their disease getting worse with Erbitux plus irinotecan, compared with a median of 2.6 months in those receiving irinotecan alone.

Colorectal cancer with BRAF V600E mutation

Two studies looked at the effect of treatment with Erbitux combined with a BRAF inhibitor in patients whose cancer had the BRAF V600E mutation.

One main study involved 479 patients whose cancer had not previously been treated. Patients received either Erbitux in combination with encorafenib plus FOLFOX or a standard oxaliplatin-based chemotherapy. Patients who received Erbitux with encorafenib and FOLFOX lived for a median time of 12.8 months without their disease getting worse, compared with 7.1 months for those who received the oxaliplatin-based chemotherapy. In addition, patients lived for a median time of 30.3 months when given Erbitux plus encorafenib and FOLFOX compared with a median of 15.1 months when given chemotherapy.

The second study involved 665 patients whose disease had worsened after previous treatment. In this study, those patients treated with Erbitux plus encorafenib lived for a median of 9.3 months compared with 5.9 months for patients who received Erbitux plus chemotherapy.

Squamous cell cancer of the head and neck

For cancers of the head and neck, Erbitux was investigated in two main studies.

The first study involved 424 patients with locally advanced cancer and looked at the effects of adding Erbitux to radiotherapy. The study found that when Erbitux was added to radiotherapy, patients lived for longer without their disease getting worse (median time of 24.4 months compared with a median of 14.9 months in people who received radiotherapy alone).

The second study involved 442 patients with recurrent or metastatic cancer and looked at the effects of adding Erbitux to a platinum-based chemotherapy. The results showed that survival was longer when Erbitux was added to a platinum-based chemotherapy (median time of 10.1 months compared with a median of 7.4 months).

Studies carried out with Erbitux are described in more detail in the medicine’s assessment reports.

What are the side effects and restrictions with Erbitux?

For the full list of side effects and restrictions with Erbitux, see the package leaflet.

The most common side effects with Erbitux (which may affect more than 1 in 10 people) include skin reactions such as rash, hypomagnesaemia (low blood magnesium levels), mild or moderate reactions linked to the infusion (such as fever, chills, dizziness and difficulty breathing).

The most common side effects with Erbitux when used with encorafenib include tiredness, nausea (feeling sick), diarrhoea, dermatitis acneiform (a skin condition that causes small, raised, acne-like bumps to form, usually on the face, scalp, chest and upper back), abdominal (belly) pain, pain in the muscles or joints, decreased appetite, rash and vomiting.

The most common side effects with Erbitux when used with encorafenib and FOLFOX include peripheral neuropathy (nerve damage in arms and legs causing pain or numbness), neutropenia (low levels of neutrophils, a type of white blood cell), tiredness, anaemia (low levels of red blood cells causing tiredness and pale skin), diarrhoea, vomiting, decreased appetite, rash, thrombocytopenia (low levels of blood platelets which can lead to bleeding and bruising), abdominal pain, haemorrhage (bleeding), pain in the muscles or joints, fever, constipation, mucosal (moist body surfaces) inflammation and infection.

Erbitux must not be used with oxaliplatin-containing chemotherapy for metastatic colorectal cancer in patients with mutated RAS or for whom RAS status is unknown.

Why is Erbitux authorised in the EU?

Erbitux has been shown to increase the time patients with certain metastatic colorectal cancers or squamous cell cancer of the head and neck lived without their cancer getting worse or to increase how long they survived. Regarding safety, the side effects with Erbitux are considered acceptable.

The European Medicines Agency therefore decided that Erbitux's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Erbitux?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Erbitux have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Erbitux are continuously monitored. Suspected side effects reported with Erbitux are carefully evaluated and any necessary action is taken to protect patients.

Other information about Erbitux

Erbitux received a marketing authorisation valid throughout the EU on 29 June 2004.

Further information on Erbitux, including the package leaflet and assessment reports, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/erbitux.

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 07-2026.