

Erbitux® 5 mg/mL solution for infusion

Cetuximab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Erbitux is and what it is used for
2. What you need to know before you use Erbitux
3. How to use Erbitux
4. Possible side effects
5. How to store Erbitux
6. Contents of the pack and other information

1. What Erbitux is and what it is used for

What Erbitux is

Erbitux contains cetuximab, a monoclonal antibody. Monoclonal antibodies are proteins that specifically recognise and bind to other unique proteins called antigens. Cetuximab binds to the epidermal growth factor receptor (EGFR), an antigen on the surface of certain cancer cells. EGFR activates proteins called RAS. RAS proteins play an important role in the EGFR pathway - a complex signalling cascade which is involved in the development and progression of cancer. As a result of this binding, the cancer cell can no longer receive the messages it needs for growth, progression and metastasis.

What Erbitux is used for

- Erbitux is used to treat two different types of cancer:
- metastatic cancer of the large intestine. In these patients, Erbitux is used alone or in combination with other anticancer medicines.
 - a certain type of cancer of the head and neck (squamous cell cancer). In these patients, Erbitux is used in combination with radiation therapy or with other anticancer medicines.

2. What you need to know before you use Erbitux

Do not use Erbitux

Do not use Erbitux if you have ever had a severe hypersensitivity (allergic) reaction to cetuximab.

Before starting treatment for metastatic cancer of the large intestine your doctor will test your cancer cells if they contain the normal (wild-type) or mutant form of RAS. You must not receive Erbitux in combination with other anticancer treatment containing oxaliplatin if your cancer cells contain the mutant form of RAS.

Warnings and precautions

Talk to your doctor before using Erbitux, if any of the following information is not clear.

Erbitux may cause infusion-related side effects. Such reactions may be allergic in nature. Please read 'Infusion-related side effects' in section 4 for details, as they may have serious consequences for you, including life-threatening conditions. These side effects normally occur during the infusion, within 1 hour afterwards, or sometimes also after this period. To recognise early signs of such effects, your condition will be checked regularly while you receive each infusion of Erbitux and for at least 1 hour afterwards.

You are more likely to experience severe allergic reactions if you are allergic to red meat, or tick bites or had positive results for certain antibodies (seen in a test). Your doctor will discuss appropriate measures with you.

Erbitux may cause side effects concerning the skin. Your doctor will discuss with you whether you may need any preventive measures or early treatment. Please also read 'Side effects concerning the skin' in section 4 for details, as some skin reactions may have serious consequences for you, including life-threatening conditions.

If you have heart problems, your doctor will discuss with you whether you can receive Erbitux in combination with other anticancer medicines, especially if you are 65 years of age or older.

Erbitux may cause side effects concerning the eyes. Please tell your doctor, if you have acute or worsening eye problems such as blurred vision, eye pain, red eyes and/or severe dry eye, if you have had such problems in the past or if you use contact lenses. Your doctor will discuss with you whether you need to consult a specialist.

If you receive Erbitux in combination with anticancer medicines including platinum, it is more likely that your white blood cell count may be reduced. Your doctor will therefore monitor your blood and general condition for signs of infection (see also 'Side effects in combination with other anticancer treatments' in section 4).

If you receive Erbitux in combination with other anticancer medicines, including fluoropyrimidines, it may be more likely that you experience heart problems which may be life-threatening. Your doctor will discuss with you whether you may need any particular supervision (see also 'Side effects in combination with other anticancer treatments' in section 4).

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Other medicines and Erbitux

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Breast-feeding

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Reporting of side effects

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Marketing Authorisation Holder:

Common side effects

4. Possible side effects

Infusion-related side effects

Mild or moderate infusion-related side effects include:

Severe infusion-related side effects include:

Side effects of which the frequency is not known (cannot be estimated from the available data)

Side effects in combination with other anticancer treatments

Keep medicines out of reach of children

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