ERBITUX®

cetuximab (rmc)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ERBITUX.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of treating you with ERBITUX against the benefits expected for you.

If you have any concerns about receiving this medicine, talk to your doctor, nurse or the hospital pharmacist.

Keep this leaflet while you are being treated with ERBITUX.

You may need to read it again.

What ERBITUX is used for

ERBITUX is used to treat certain cancers that have a protein on their cell surface called epidermal growth factor receptor (EGFR). When a growth factor called EGF attaches to EGFR it turns on signals within the cell causing it to grow and divide to form more cells. In many human tumours, there is an over-activation of these receptors, which leads to increased uncontrolled growth of cancer cells and development into a tumour.

How ERBITUX works

The active substance in ERBITUX is cetuximab. It belongs to a group of medicines called monoclonal antibodies. Monoclonal antibodies are proteins that specifically recognise and attach to other unique proteins. ERBITUX attaches to the EGFR more tightly than EGF and thereby interferes with the growth of cancer cells.

What ERBITUX does

ERBITUX is used to treat metastatic colorectal cancer (cancer of the colon or large intestine and rectum that has spread to other parts of the body). It may be used alone or in combination with certain types of medicines called chemotherapy to treat metastatic colorectal cancer.

Before you are prescribed ERBITUX, your doctor will test your cancer cells to see if they contain either the normal (wild-type) or mutant forms of genes called RAS. ERBITUX is used to treat patients who express normal RAS genes.

ERBITUX is used to treat locally advanced head and neck cancer, in combination with radiation therapy. It is also used to treat head and neck cancer that has reoccurred or spread to other parts of the body in combination with certain types of chemotherapy.

Ask your doctor if you have any questions about why ERBITUX has been prescribed for you.

Your doctor may have prescribed it for another reason.

Use in Children

The effectiveness of ERBITUX in children under the age of 18 years has not been established.

Before you are given ERBITUX

When you must not be given it

Do not use ERBITUX:

- if your cancer cells have been found to contain a mutant form of the RAS gene or if your RAS status is not known (particularly, in combination with anticancer treatments containing oxaliplatin)
- if you experience severe hypersensitivity (allergic) reactions to cetuximab
- if you are allergic to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

If you have had an allergic reaction to ERBITUX, your doctor will decide whether or not you can receive it again. This will depend on the severity of your reaction.

If you receive ERBITUX in combination with chemotherapy medicines, ask your doctor or pharmacist for the Consumer Medicine Information for these medicines.

Do not use ERBITUX after the expiry date printed on the pack.

The nurse or hospital pharmacist will check the expiry date before giving ERBITUX to you.

Do not use ERBITUX if the packaging is torn or shows signs of tampering.

The nurse will check this for you.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start treatment with ERBITUX

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- abnormal blood test results
- liver problems
- kidney problems
- heart problems

  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.
- lung problems or difficulty in breathing
- acute or worsening eye problems such as blurred vision, eye pain, red eyes and/or severe dry eye, or if you use contact lenses.
- history of allergy to red meat, tick bites or to α-1-galactose

Tell your doctor if you are pregnant or plan to become pregnant.

ERBITUX is not recommended for use during pregnancy. Make sure you maintain adequate contraception during treatment and for two months after your last dose.

Tell your doctor if you are breastfeeding or wish to breastfeed during this time.

You should not breastfeed during treatment and for 2 months after your last dose.

If it is necessary for you to use ERBITUX, your doctor will discuss the risks and benefits of having it if you are pregnant or breastfeeding.

If you have not told your doctor about any of the above, tell them before you are given ERBITUX.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without prescription from your pharmacy, supermarket, naturopath or health food shop.

These medicines may be affected by ERBITUX or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while using ERBITUX.

If your doctor is giving you other medicines, such as chemotherapy, with ERBITUX, or is also treating you with radiation, he/she will discuss with you the benefits and risks involved.

How ERBITUX is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

A doctor experienced in the use of medicines for cancer will supervise your treatment with ERBITUX. Trained nurses will administer ERBITUX to you.

ERBITUX is usually given once a week by intravenous infusion (slow injection into a vein).

Before receiving the first dose, you should be given anti-allergy medicines (an antihistamine and a corticosteroid) at least 1 hour prior to receiving ERBITUX to minimise the chances of an allergic reaction. Pre-treatment with an antihistamine and a corticosteroid is also recommended for the following weekly doses.

Your doctor may also prescribe oral antibiotics or a topical steroid cream for your skin before you are given ERBITUX. This may help prevent or minimise skin reactions.

ERBITUX may be administered either diluted or undiluted. Your doctor will determine the correct dose and dilution for you. If you are being treated with a chemotherapy medicine in combination with ERBITUX, the chemotherapy medicine can only be started 1 hour after the end of the ERBITUX infusion.

How much to use

Your doctor will calculate the correct dose of ERBITUX for you because it depends on your body surface area (a measurement based on your height and weight).

The first dose is given over a period of approximately 2 hours via infusion.

The following weekly doses are infused over a period of approximately 1 hour.

How long to use ERBITUX for

Your doctor will decide how long you will receive ERBITUX based on your response to the medicine and the type of cancer you have.

If you miss a dose

If you miss a dose, talk to your doctor or nurse and arrange another visit as soon as possible.

If you are given too much (overdose)

As ERBITUX is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects after being given it, tell your doctor immediately.

Immediately contact your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia; 0800 POISON or 0800 764766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much ERBITUX.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are being treated with ERBITUX

Things you must do

Keep all appointments with your doctor and always discuss anything that worries you during or after treatment with ERBITUX.

Your doctor may conduct blood tests before starting ERBITUX and from time to time during treatment. This is to make sure the medicine is working and to check for unwanted side effects.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are receiving ERBITUX.

Tell any other doctors, dentists and pharmacists who treat you that you are receiving ERBITUX.

If you become pregnant while you are treated with ERBITUX, tell your doctor immediately.

Limit your exposure to sunlight by wearing a hat, protective clothing and SPF 30+ or higher sunscreen when you go outside.

Sun exposure may make your skin reactions worse.

Things to be careful of

Be careful driving or operating machinery until you know how ERBITUX affects you.

Treatment-related symptoms can affect your concentration and ability to react.

Side effects

All medicines, including ERBITUX, can have unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Most of the side effects occur during or soon after ERBITUX therapy. However, some may occur after this period.

Tell your doctor or nurse as soon as possible if you do not feel well while you are having ERBITUX.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Infusion-related side effects

Tell your doctor or nurse if you experience any of the following symptoms, during or after treatment with ERBITUX:

- fever
- chills
- shortness of breath
- dizziness.

Mild to moderate infusion-related reactions may occur in more than 1 in 10 people who are being treated with ERBITUX. To recognise early signs of these side effects, you will be monitored closely while you are receiving each infusion and for at least 1 hour afterwards.

Your doctor may consider reducing the infusion rate of ERBITUX in order to manage these symptoms.

Sometimes these side effects may occur up to several hours later.

If you experience them any time after receiving ERBITUX, contact your doctor or nurse.

Tell your doctor or nurse immediately if you experience any of the following side effects:

- asthma-like symptoms such as severe breathing difficulties with wheezing, hoarseness, and difficulty speaking
- a rapidly developing lumpy rash
- chest pain
- leg pain
- feeling dizzy or faint.

These side effects (which may occur in more than 1 in 100 people who are being treated with ERBITUX) can be life-threatening and need immediate medical attention. Treatment with ERBITUX may have to be stopped.

Skin reactions

Tell your doctor if you notice any of the following symptoms of skin reaction and they worry you:

- acne-like skin rash
- itchy, dry, scaling skin
- excessive growth of hair on your body
- nail problems.

Skin reactions are very common. More than 8 in 10 people receiving ERBITUX may experience skin reactions.

Most of these side effects develop within the first three weeks of treatment. They usually disappear over time after the end of ERBITUX therapy.

Tell your doctor or nurse immediately if you experience:

- severe blistering or peeling of the skin.

  These can be symptoms of a very rare (may affect less than 1 in 10,000 people) but severe skin reaction which may have serious consequences and can be life-threatening.

- already affected areas of your skin getting worse, especially if you also experience general signs of infection such as fever and tiredness.

  These signs may indicate a skin infection, which may have serious consequences including life-threatening conditions.

Tell your doctor if you notice any other extensive skin rash.

Depending on how severe your skin reaction is and how often it occurs, your doctor may:

- stop ERBITUX for up to 2 weeks before giving you the next dose,
- administer a lower dose, or
- stop treatment altogether.

Your doctor may also prescribe oral antibiotics or a topical steroid cream to help manage any skin reactions that you may have.

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following:

- red, watery eye(s) which can be accompanied by pain and blurring of your vision, eye sore, severe dry eye(s) or crusty eyelids
- weakness, fatigue, loss of appetite, weight loss, vomiting or nausea (feeling sick). These symptoms may be due to low levels of magnesium, calcium or other electrolytes in your blood.
- abdominal pain or diarrhoea
- sore, red or dry mouth, which may be accompanied by a nose bleed
- signs of frequent infections such as fever, tiredness, chills, sore throat or mouth ulcers
- headache
- leg swelling or pain (signs of a blood clot)
- chest pain or tightness
- sudden-onset fever, severe headache, vomiting, stiff neck and sensitivity to light.

Tell your doctor immediately if you experience sudden or worsened breathing difficulties, especially if you also experience cough or fever.

These can be symptoms of lung inflammation, which is rare (may affect less than 1 in 1,000 people) but can be life-threatening. Your treatment with ERBITUX may have to be interrupted or stopped altogether.

Side effects in combination with chemotherapy or radiation therapy

If you receive ERBITUX in combination with chemotherapy medicines or radiation therapy, you may also experience some side effects from the chemotherapy medicine or the radiation therapy or from the combination of ERBITUX with these treatments.

Tell your doctor immediately if you experience:

- signs of frequent infections such as fever, tiredness, chills, sore throat or mouth ulcers.

  If you receive ERBITUX in combination with chemotherapy including platinum, it is more likely that your white blood cell count may be reduced. You may experience the above symptoms and infectious complications which can include life-threatening conditions.
- chest pain
- redness and swelling of the palms of the hands or the soles of the feet which may cause the skin to peel.

  If you receive ERBITUX in combination with chemotherapy containing fluoropyrimidines, it is more likely that you may experience some of the above symptoms.

Tell your doctor or nurse if you experience:

- sore, red or dry mouth, which may be accompanied by a nose bleed
- severe flaking or peeling of the skin
- difficulty swallowing.

If you receive ERBITUX in combination with radiation therapy, you may experience some of the above symptoms.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After being treated with ERBITUX

Storage

ERBITUX must be kept in a refrigerator at 2° to 8°C, but it must not be frozen.

Each vial is intended for single use only. When the needed amount of solution has been withdrawn from the vial, any remaining solution must be discarded.

Product description

What it looks like

ERBITUX is a clear, colourless solution. It is supplied in 20 mL or 100 mL colourless glass vials with a rubber stopper and aluminium seal. Each pack contains 1 vial.

Ingredients

The active ingredient in ERBITUX is cetuximab. Each 20 mL vial contains 100 mg cetuximab and each 100 mL vial contains 500 mg cetuximab.

The solution also contains the following inactive ingredients:

- glycine
- polysorbate 80
- citric acid monohydrate

- sodium chloride
- water for injections
- sodium hydroxide.

ERBITUX solution does not contain any preservative.

Supplier

ERBITUX is supplied in Australia by:

Merck Healthcare Pty Ltd

Suite 1, Level 1

Building B

11 Talavera Road

Macquarie Park NSW 2113

ERBITUX is supplied in New Zealand by:

Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks

Auckland

For enquiries about ERBITUX please call Merck Medical Information on 1800-MED-INF (1800-633-463) or from New Zealand call 0800 426 252.

Australian registration numbers

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