

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ERBITUX?

ERBITUX contains the active ingredient cetuximab. ERBITUX is used to treat metastatic colorectal cancer, locally advanced head and neck cancer, and recurrent/metastatic head and neck cancer.

For more information, see Section [1. Why am I using ERBITUX?](#) in the full CMI.

2. What should I know before I use ERBITUX?

Do not use if your cancer cells have been found to contain a mutated form of the RAS gene, if your RAS status is not known, or if you have ever had an allergic reaction to ERBITUX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ERBITUX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ERBITUX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ERBITUX?

- 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.
- The first dose is approximately 2 hours via infusion. The following doses are every week (1 hour infusion period) or every 2 weeks (2 hours infusion period).

More instructions can be found in Section [4. How do I use ERBITUX?](#) in the full CMI.

5. What should I know while using ERBITUX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, dentist or pharmacist you visit that you are using ERBITUX.• Maintain adequate contraception during treatment and for two months after your last dose.• Limit your exposure to sunlight. Wear a hat, protective clothing and sunscreen when you go outside.• Keep all appointments with your doctor so that your progress can be checked.
Driving or using machines	<ul style="list-style-type: none">• Treatment-related symptoms can affect your concentration and ability to react. Be careful until you know how ERBITUX affects you.

For more information, see Section [5. What should I know while using ERBITUX?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headache; conjunctivitis; diarrhoea; nausea; vomiting; skin reactions; low magnesium/calcium levels in the blood; dehydration; loss of appetite, leading to weight loss; infusion-related reactions; sore, red mouth (which may lead to nosebleeds); tiredness; increased infections in combination with chemotherapy; increased radiation-related effects in combination with radiotherapy; increased liver enzyme levels.

Serious side effects include inflammation of the lining of the brain; blood clots; lung inflammation; severe blistering or peeling of the skin; skin infections; heart failure/attack; low white cell count.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ERBITUX®

Active ingredient(s): *cetuximab (rnc)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ERBITUX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ERBITUX.**

Where to find information in this leaflet:

- [1. Why am I using ERBITUX?](#)
- [2. What should I know before I use ERBITUX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ERBITUX?](#)
- [5. What should I know while using ERBITUX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ERBITUX?

ERBITUX contains the active ingredient cetuximab.

ERBITUX is a monoclonal antibody. Monoclonal antibodies are proteins that specifically recognise and attach to other unique proteins.

When a growth factor called an epidermal growth factor (EGF) attaches to an epidermal growth factor receptor (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. ERBITUX attaches to the EGFR more tightly than EGF and thereby interferes with the growth of cancer cells.

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.
- Locally advanced head and neck cancer, in combination with radiation therapy.
- Recurrent/metastatic head and neck cancer (cancer of the head and neck that has reoccurred or spread to other parts of the body) in combination with certain types of chemotherapy.

2. What should I know before I use ERBITUX?

If you have metastatic colorectal cancer, your doctor will order tests to see if ERBITUX is suitable for you. The test will check if your cancer cells contain either the normal (wild-type) or mutated forms of genes called RAS. ERBITUX is used to treat patients who express normal RAS genes.

Warnings

Do not use ERBITUX if:

- You are allergic to cetuximab, or any of the ingredients listed at the end of this leaflet. 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.

- Always check the ingredients to make sure you can use this medicine.
- If your cancer cells have been found to contain a mutated form of the RAS gene or if your RAS status is not known (particularly, in combination with anticancer treatments containing oxaliplatin).

Check with your doctor if you have any other medical conditions, including:

- 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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

Use in children

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ERBITUX and affect how it works.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ERBITUX.

4. How do I use ERBITUX?

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 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.

How much to use

- A doctor experienced in the use of medicines for cancer will supervise your treatment with ERBITUX. Trained nurses will administer ERBITUX to you.
- ERBITUX may be administered either diluted or undiluted. Your doctor will determine the dilution for you.
- 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 doses are infused over a period of approximately 1 hour for weekly infusions or 2 hours for every two week infusions.
- Your doctor will decide how long you will receive ERBITUX based on your response to the medicine and the type of cancer you have.

When to use ERBITUX

- ERBITUX is either given once a week or once every two weeks by intravenous infusion (slow injection into a vein).
- 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.

If you use too much ERBITUX

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 think that you have been given too much ERBITUX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ERBITUX?

Things you should do

Keep all appointments with your doctor so that your progress can be checked. Your doctor may also 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 miss an appointment, call your healthcare provider to reschedule.

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.

Call your doctor straight away if you:

- become pregnant while you are treated with ERBITUX

Remind any doctor, nurse, dentist or pharmacist you visit that you are using ERBITUX.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ERBITUX affects you.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects

Less serious side effects	What to do
<p>Infusion-related:</p> <ul style="list-style-type: none"> • Fever, chills, shortness of breath, dizziness <p>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.</p> <p>Your doctor may consider reducing the infusion rate of ERBITUX in order to manage these symptoms.</p> <p>Sometimes these side effects may occur up to several hours later.</p> <p>If you experience them any time after receiving ERBITUX, contact your doctor or nurse.</p> <p>Skin-related:</p> <ul style="list-style-type: none"> • Acne-like rash • Itchy, dry, scaling skin • Excessive growth of hair on your body 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> Nail problems <p>These skin-related side effects can develop within the first three weeks of treatment. They usually disappear over time after the end of ERBITUX therapy.</p> <p>Other:</p> <ul style="list-style-type: none"> headache red, watery eye(s) which can be accompanied by pain and blurring of your vision, eye sore, severe dry eye(s) or crusty eyelids abdominal pain or diarrhoea weakness, fatigue, loss of appetite, weight loss, vomiting or nausea (feeling sick). These symptoms may be due to low levels of magnesium, calcium, other electrolytes or high levels of liver enzymes in your blood. feeling dehydrated sore, red or dry mouth, which may be accompanied by a nosebleed signs of frequent infections such as fever, tiredness, chills, sore throat or mouth ulcers chest pain or tightness sudden-onset fever, severe headache, vomiting, stiff neck and sensitivity to light. <p>In combination with radiation therapy:</p> <ul style="list-style-type: none"> sore, red or dry mouth, which may be accompanied by a nosebleed severe flaking or peeling of the skin difficulty swallowing 	

Serious side effects

Serious side effects	What to do
<p>Infusion-related:</p> <ul style="list-style-type: none"> Asthma-like symptoms such as severe breathing difficulties with wheezing, hoarseness, hives and difficulty speaking. A rapidly developing lumpy rash, chest pain, leg pain, feeling dizzy or faint. <p>Skin-related:</p> <ul style="list-style-type: none"> Severe blistering or peeling of the skin (Stevens-Johnson syndrome) Already affected areas of your skin getting worse, especially if you also experience general signs of infection such as fever and tiredness. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>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:</p> <ul style="list-style-type: none"> stop ERBITUX for up to 2 weeks before giving you the next dose, administer a lower dose, or stop treatment altogether. <p>Other:</p> <ul style="list-style-type: none"> sudden or worsened breathing difficulties, especially with cough or fever (lung inflammation) inflammation of the lining of the brain (aseptic meningitis) leg swelling or pain (signs of a blood clot) blood clots in the lungs <p>In combination with chemotherapy:</p> <ul style="list-style-type: none"> signs of frequent infections such as fever, tiredness, chills, sore throat or mouth ulcers (reduced white blood cell count, which can lead to fever, pneumonia, and infection in the blood). chest pain (symptom of heart attack or heart failure) redness and swelling of the palms of the hands or the soles of the feet which may cause the skin to peel (hand-foot syndrome). 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ERBITUX contains

Active ingredient (main ingredient)	Cetuximab (rnc)
Other ingredients (inactive ingredients)	Glycine, polysorbate 80, citric acid monohydrate, sodium chloride, water for injections, sodium hydroxide
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What ERBITUX looks like

ERBITUX is a clear to slightly opalescent, colourless to yellowish 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. (Aust R 132393, 132396).

Who distributes ERBITUX

Merck Healthcare Pty Ltd

Suite 1, Level 1

Building B

11 Talavera Road

Macquarie Park NSW 2113

Medical Information: 1800 633 463

Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks

Auckland

Medical Information: 0800 426 252

This leaflet was prepared in November 2023.

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