

CYRAMZA®

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 CYRAMZA?

CYRAMZA contains the active ingredient ramucirumab (rmc) and is used to treat advanced stomach cancer (including cancer of the junction between the oesophagus and the stomach).

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

2. What should I know before I use CYRAMZA?

Do not use if you have ever had an allergic reaction to ramucirumab 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 CYRAMZA?](#) in the full CMI.

3. What if I am taking other medicines?

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

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 and **check with your doctor or pharmacist if you are not sure if these will affect CYRAMZA.**

4. How will CYRAMZA be given?

- CYRAMZA is given as an infusion (drip) into your veins over approximately 60 minutes.
- CYRAMZA is given once every two weeks as part of the treatment cycle. Your doctor will advise how many treatment cycles you need.

More instructions can be found in Section [4. How will CYRAMZA be given?](#) in the full CMI.

5. What should I know while using CYRAMZA?

Things you should do	
	<ul style="list-style-type: none">• Tell your doctor immediately if you become pregnant while

	<p>being treated with CYRAMZA.</p> <ul style="list-style-type: none"> ● Tell your doctor immediately if you notice any changes in your movement or behaviour. ● Remind any doctor, dentist or pharmacist you visit that you are being treated with CYRAMZA, especially if you are about to start a new medicine. ● If you are going to have surgery, tell the surgeon or anaesthetist that you are being treated with CYRAMZA. ● Tell your doctor if you develop a poorly healing wound. ● Monitor your blood pressure regularly.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how CYRAMZA affects you.

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

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Becoming more prone to getting infections, diarrhoea, soreness inside your mouth, feeling tired or weak, swelling in your hands and lower legs, nose bleed, stomach pain and high blood pressure were very commonly reported in patients using CYRAMZA. Serious side effects may include clotting in your arteries which may lead to heart attack or stroke, tear or rupture in your arteries, bleeding or a tear in your gut, severe allergic reaction, or vision loss associated with headaches, confusion and seizures.

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.

CYRAMZA®

Active ingredient: *Ramucirumab (rmc)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CYRAMZA. **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 CYRAMZA.**

Where to find information in this leaflet:

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

1. Why am I using CYRAMZA?

CYRAMZA contains the active ramucirumab.

CYRAMZA belongs to a group of medicines known as antineoplastic (anti-cancer) agents. They may also be called chemotherapy medicines. It works by cutting off the blood supply that allows cancer cells to grow.

CYRAMZA may be used in combination with other chemotherapy drugs.

CYRAMZA is used to treat advanced stomach cancer (including cancer of the junction between the oesophagus and the stomach).

2. What should I know before I use CYRAMZA?

Warnings

Do not use CYRAMZA if:

- you are **allergic to ramucirumab, or any of the ingredients listed** at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other conditions or are taking any other medicines that may **increase your risk of bleeding or impact on your body's blood clotting ability**. CYRAMZA may further increase your risk of bleeding.
- have **high blood pressure**. Your doctor will make sure that your blood pressure is brought under control before starting CYRAMZA as it may worsen once you start treatment.
- have **severe liver disease** ('cirrhosis') and associated conditions, such as **excessive water retention in**

your stomach ('ascites'). This will help your doctor determine if CYRAMZA is right for you.

- are **going to have surgery**, if you have had **recent surgery**, or if you have a **poorly healing wound** as CYRAMZA may impair your body's ability to heal itself. This will help your doctor determine when to start your treatment with CYRAMZA.
- have or have had an **enlargement and weakening of a blood vessel wall (aneurysm)** or a **tear in a blood vessel wall (artery dissection)**. This will help your doctor determine if CYRAMZA is right for you.

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?](#)

Taking Pre-medication

Your doctor may give you another medicine in your infusion (drip) before they give you CYRAMZA. This is known as 'pre-medication'.

Pre-medication may reduce your risk of developing an infusion-related reaction. See additional information on infusion-related reactions under Section [6. Are there any side effects](#)

If you experience a infusion-related reaction with CYRAMZA, you will be given pre-medication for all future infusions.

Pregnancy and breastfeeding

Pregnancy and breastfeeding should be avoided during CYRAMZA treatment and for at least 3 months after the last dose of CYRAMZA. Your doctor can discuss with you the risks and benefits involved.

Use in children

This medicine is not recommended for use in children under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

3. What if I am taking other medicines?

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

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 and **check with your doctor or pharmacist if you are not sure if these will affect CYRAMZA.**

4. How will CYRAMZA be given?

How much is given

Your doctor will decide the dosage of CYRAMZA you are given. This will depend on your weight.

How it is given

CYRAMZA is given as an infusion (drip) into your veins over approximately 60 minutes. You may also be given other chemotherapy medicines at the same time.

If you experience an infusion-related reaction during treatment, your doctor or nurse will increase your infusion time.

Your doctor or nurse will always prepare and administer the CYRAMZA infusion for you. **You should never do this yourself.**

How often is it given

CYRAMZA is given once every two weeks as part of the treatment cycle.

Your doctor will advise how many treatment cycles you will need.

If you have been given too much CYRAMZA

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

However, if you experience any unexpected or worrying side effects after being given CYRAMZA, immediately tell your doctor or nurse or go to the Emergency Department at your nearest hospital.

You may need urgent medical attention.

5. What should I know while using CYRAMZA?

Things you should do

- Tell your doctor immediately **if you become pregnant** while being treated with CYRAMZA. Pregnancy and breastfeeding should be avoided during CYRAMZA treatment and for at least 3 months after the last dose of CYRAMZA.
- Tell your doctor immediately if you notice any **changes in your movement or behaviour**. This may be due to a blood clot that may lead to a stroke.
- Tell your doctor immediately if you experience any signs of heart failure, such as **trouble breathing, dry cough, swelling in your ankles, legs or abdomen, or dizziness and tiredness**. Your doctor may consider stopping your treatment with CYRAMZA.

- Remind any doctor, dentist, or pharmacist that you visit that you are being treated with CYRAMZA, **especially if you are about to start on any new medicine.**
- **If you are going to have surgery**, tell the surgeon or anaesthetist that you are being treated with CYRAMZA. CYRAMZA may impair your body's ability to heal itself. Your doctor will stop your treatment with CYRAMZA for at least 4 weeks before you have surgery and will decide when it should re-start.
- Tell your doctor **if you have any wounds** that are not healing as quickly as they normally would. CYRAMZA may impair your body's ability to heal itself and your doctor may decide to temporarily stop your treatment with CYRAMZA until they have healed.
- **Monitor your blood pressure regularly** while you are being treated with CYRAMZA as your blood pressure may increase during treatment. If you develop severe high blood pressure, your doctor may choose to prescribe blood pressure lowering medication or to temporarily stop your treatment with CYRAMZA until your blood pressure is under control. If your high blood pressure cannot be controlled, your doctor may choose to permanently stop your treatment with CYRAMZA .
- **Keep all of your doctor's appointments** so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- **The amount of protein in your urine will be checked regularly** during your treatment with CYRAMZA. Your doctor may decide to change your

dose or delay your treatment depending on your general condition and if your urine protein levels are too high. If you are passing more than a certain amount of protein with your urine or if you develop severe kidney disease, your doctor may choose to permanently stop your treatment with CYRAMZA .

- **If you are about to have any blood tests**, tell your doctor that you are receiving this medicine.

Driving or using machines

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

It is not known whether CYRAMZA will affect your ability to drive or to use machines. If you experience any symptoms that affect your ability to concentrate and react: do not drive, operate machinery, or do anything else that could be dangerous until the effect goes away.

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.

When used in combination with other chemotherapy medicine, also refer to their consumer medicine information leaflet for a list of other possible side effects.

Less serious side effects

Less serious side effects	What to do
<p>General disorders:</p> <ul style="list-style-type: none">• swelling of the hands, feet and legs due the body retaining water• inflammation or soreness of the mouth• hoarse, rough, or raspy voice• Low white blood cell levels: symptoms may include fever, chills, sweating, sore throat or other signs of infection• feeling tired or weak, or lacking in energy• high blood pressure <p>Stomach related:</p> <ul style="list-style-type: none">• diarrhoea• stomach pain• blockage of the gut: symptoms may include constipation and stomach pain <p>Bleeding related:</p>	<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"> ● nose bleed ● bleeding or bruising more easily than normal <p>Blood-test related:</p> <ul style="list-style-type: none"> ● low blood levels of potassium which can cause muscle weakness, twitching, or abnormal heart rhythm ● low blood levels of sodium which can cause tiredness and confusion or muscle twitching ● low blood levels of thyroid hormone which can cause tiredness, weight gain, and feeling cold <p>Brain related:</p> <ul style="list-style-type: none"> ● headache <p>Kidney related:</p> <ul style="list-style-type: none"> ● high levels of protein in the urine: symptoms may include more frequent urination, shortness of breath, tiredness, swelling 	

Less serious side effects	What to do
<p>of your hands, feet, stomach or face.</p> <p>Blood vessel related:</p> <ul style="list-style-type: none"> ● a collection of small blood vessels that form a lump under the skin, sometimes known as a 'strawberry mark'. ● clotting in small blood vessels, most commonly in the kidneys or the brain. Symptoms may include confusion, sleepiness, seizures (brain), less frequent urination, swollen legs, high blood pressure (kidneys), shortness of breath, bleeding or bruising more easily, fever (both brain and kidneys). 	

Serious side effects

Serious side effects	What to do
<p>Stomach related:</p> <ul style="list-style-type: none"> ● hole in the wall of your gut: symptoms include severe stomach pain, vomiting, fever, or chills. ● severe bleeding in your gut: symptoms may include extreme tiredness, weakness, dizziness or changes in the colour of your stools. ● Abnormal tube-like connections or passageways inside the body (fistula): symptoms will depend on the location of the fistula, but may include diarrhoea, infection of the urine (burning with urination, cloudy or bloody urine), pain in the abdominal area. <p>Blood vessel related:</p> <ul style="list-style-type: none"> ● blood clots in the arteries can lead to 	<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> <p>CYRAMZA may be permanently stopped if you develop any of these side effects.</p>

Serious side effects	What to do
<p>a heart attack or stroke. Symptoms of a heart attack may include chest pain or heaviness in the chest. Symptoms of a stroke may include sudden numbness or weakness of the arm, leg and face, feeling confused, difficulty speaking or understanding others, sudden difficulty in walking or loss of balance or coordination, memory loss, blurred or loss of vision or sudden dizziness.</p> <ul style="list-style-type: none"> ● an enlargement and weakening of a blood vessel wall (aneurysm): symptoms may include sudden and severe pain in the abdomen or back. ● tear in a blood vessel wall (artery dissections): symptoms may include sudden, 	

Serious side effects	What to do
<p>severe abdominal, chest, or back pain.</p> <p>Allergic reaction related:</p> <ul style="list-style-type: none"> ● infusion-related reactions: symptoms may include increased muscle tension, tremors, back pain and/or spasms, chest pain and/or tightness, chills, flushing, difficulty breathing, wheezing, and feeling of tingling or numbness in the hands or feet. In severe cases, symptoms may include breathing distress caused by narrowing of the airways, faster heartbeat, and feeling faint. ● sudden signs of allergy: rash, itching or hives on the skin, swelling of the face, lips or tongue or other parts of the body, shortness of breath, wheezing or trouble breathing. 	

Serious side effects	What to do
<p>Head related:</p> <ul style="list-style-type: none"> • a brain condition called posterior reversible encephalopathy syndrome (PRES): symptoms may include fits (seizures), headache, feeling sick (nausea), vomiting, loss of vision or reduced alertness, with or without high blood pressure. 	

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 CYRAMZA contains

Active ingredient (main ingredient)	ramucirumab
Other ingredients (inactive ingredients)	glycine histidine histadine hydrochloride monohydrate polysorbate 80 sodium chloride water for injections

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

What CYRAMZA looks like

CYRAMZA is a clear to slightly opalescent and colourless to slightly yellow solution and is available in a glass vial container with a rubber stopper.

CYRAMZA is available in packs of:

- 1 vial of 10 mL
- 1 vial of 50 mL

Australian Registration Numbers:

CYRAMZA 100 mg, AUST R 227351

CYRAMZA 500 mg, AUST R 227352

Not all packs may be marketed.

Who distributes CYRAMZA

CYRAMZA is supplied in Australia by:

Eli Lilly Australia Pty Limited

112 Wharf Road

WEST RYDE NSW 2114

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