YESCARTA®

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 given YESCARTA?

YESCARTA also known as axicabtagene ciloleucel is a type of medicine called a "genetically modified cell therapy". YESCARTA is used to treat adults with aggressive large B-cell lymphoma (LBCL) and follicular lymphoma (FL) affecting your lymph tissue (part of the immune system) that affects a type of white blood cell called B lymphocytes and other organs in your body. Too many of these abnormal white blood cells accumulate in your tissue and this is the cause of the symptoms you may have.

For more information, see Section 1. Why am I given YESCARTA? in the full CMI.

2. What should I know before I use YESCARTA?

Do not use if you have ever had an allergic reaction to axicabtagene ciloleucel 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 am given YESCARTA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with YESCARTA 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 am I given YESCARTA?

- YESCARTA is made specially for you as a single administration of your own modified white blood cells.
- Your doctor will give you YESCARTA by a drip (*infusion*) into a vein (*intravenously*).

More instructions can be found in Section 4. How am I given YESCARTA? in the full CMI.

5. What should I know after receiving YESCARTA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you have been given YESCARTA. • Plan to stay within proximity (i.e. within 2 hours) of the hospital where you will be treated for at least 4 weeks after you have been given YESCARTA.
Driving or using machines	• Do not drive or operate machinery in the 8 weeks after receiving YESCARTA.

For more information, see Section 5. What should I know after I am given YESCARTA? in the full CMI.

6. Are there any side effects?

There can be some serious side effects before and after YESCARTA treatment. Serious side effects may include symptoms of cytokine release syndrome (CRS), disturbances of brain function or infection.

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.

WARNING: CYTOKINE RELEASE SYNDROME

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA. Do not administer YESCARTA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

YESCARTA®

Active ingredient(s): *axicabtagene ciloleucel*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I given YESCARTA?

YESCARTA also known as axicabtagene ciloleucel is a type of medicine called a "genetically modified cell therapy". YESCARTA is made specially for you as a single administration of your own modified white blood cells. It is given by a drip (*infusion*) into a vein (*intravenously*).

YESCARTA is used to treat adults with aggressive large B-cell lymphoma (LBCL) and follicular lymphoma (FL) affecting your lymph tissue (part of the immune system) that affects a type of white blood cell called B lymphocytes and other organs in your body. Too many of these abnormal white blood cells accumulate in your tissue and this is the cause of the symptoms you may have. YESCARTA is used to treat this condition when other medicines have stopped working for you.

2. What should I know before I am given YESCARTA?

Warnings and Precautions

Do not use YESCARTA if:

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

Tell your doctor (or your doctor will check) if you:

- have problems with your nervous system (such as fits, stroke, or memory loss).
- have kidney problems.
- have low blood cell levels (blood counts).
- have any problems with your lungs, heart or blood pressure (low or high).
- have had a stem cell transplant in the last 4 months
- have signs or symptoms of graft versus host disease. This happens when transplanted cells attack your body, causing symptoms such as rash, nausea, vomiting, diarrhoea and bloody stools.
- notice the symptoms of your cancer are getting worse. If you have lymphoma this might include fever, feeling weak, night sweats, sudden weight loss.
- have an infection. The infection will be treated before the YESCARTA infusion.
- have had hepatitis B, hepatitis C or human immunodeficiency virus (HIV) infection.

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?

Plan to stay within proximity (i.e. within 2 hours) of the hospital where you will be treated for at least 4 weeks after you have been given YESCARTA.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

This is because the effects of YESCARTA in pregnant or breast feeding women are not known, and it may harm your unborn baby or your breast feeding child.

You will be given a pregnancy test before treatment starts. YESCARTA should only be given if the results show you are not pregnant.

If you are pregnant or think you may be pregnant after treatment with YESCARTA, talk to your doctor immediately.

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.

Before you are given YESCARTA tell your doctor or nurse if you are taking any medicines that weaken your immune system such as corticosteroids, since these medicines may interfere with the effect of YESCARTA. Do not start any new medicines after being given YESCARTA without first talking to your doctor or pharmacist.

In particular, you must not be given certain vaccines called live vaccines:

- In the 6 weeks before you are given the short course of chemotherapy (called lymphodepleting chemotherapy) to prepare your body for the YESCARTA cells.
- During YESCARTA treatment.
- After treatment while the immune system is recovering.

Talk to your doctor if you need to have any vaccinations.

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

4. How am I given YESCARTA?

Tests and Checks

Before you are given YESCARTA your doctor will:

- Check your lungs, heart and blood pressure.
- Look for signs of infection; any infection will be treated before you are given YESCARTA.
- Check if your cancer is getting worse.
- Look for signs of graft-versus-host disease that can happen after a transplant.
- Check your blood for uric acid and for how many cancer cells there are in your blood. This will show if you are likely to develop a condition called *tumour lysis syndrome*. You may be given medicines to help prevent the condition.
- Check for hepatitis B, hepatitis C or HIV infection.
- Check if you had a vaccination in the previous 6 weeks or are planning to have one in the next few months.

How much you will be given

- Since YESCARTA is made from your own white blood cells, your cells will be collected from you to prepare your medicine.
- Your doctor will take some of your blood using a catheter placed in your vein (a procedure call leukapheresis [loo-kah-fur-ee-sis]).
- Some of your white blood cells are separated from your blood and the rest of your blood is returned to your vein. This can take 3 to 6 hours and may need to be repeated.
- Your white blood cells are sent away to make YESCARTA. It usually takes about 3 to 4 weeks to receive your YESCARTA therapy but the time may vary.
- Prior to receiving YESCARTA, you will be given preparative chemotherapy (called lymphodepleting chemotherapy), which will allow your modified white blood cells in YESCARTA to multiply in your body when the medicine is given to you.
- Your doctor or nurse will check carefully that this medicine is yours.
- In some cases, it might not be possible to go ahead with the planned treatment with YESCARTA. For example: if YESCARTA infusion is delayed for more than 2 weeks after you have received preparatory chemotherapy you may have to receive more preparative chemotherapy.

How you are given YESCARTA

- **YESCARTA will always be given to you by a healthcare professional.**
- **YESCARTA is a single infusion treatment.**
- **During the 30 to 60 minutes before you are given YESCARTA you may be given other medicines. This is to help prevent infusion reactions and fever.**

  These other medicines may include:

  - **Paracetamol**
  - **An antihistamine such as diphenhydramine or similar.**
- Your doctor or nurse will give you a single infusion of YESCARTA into your vein for approximately 30 minutes.
- YESCARTA is the genetically modified version of your normal white blood cells. Your healthcare professional handling YESCARTA will therefore take appropriate precautions (wearing gloves and glasses) to avoid potential transmission of infectious diseases and will follow local biosafety guidelines to clean up or dispose of any material that has been in contact with YESCARTA.
- **You must receive YESCARTA infusion in a qualifed clinical facility and be discharged only when your doctor thinks it is safe for you to go home.**
- You will be monitored where you received your treatment daily for at least 7 days after the infusion.
- Your doctor may do blood tests to check for side effects.

5. What should I know after I am given YESCARTA?

Things you should do

Plan to stay within proximity of the hospital where you were treated for at least 4 weeks after you have been given YESCARTA.

Your doctor will recommend that you return to the hospital daily for at least 7 days and will consider whether you need to stay at the hospital as an inpatient for at least 7 days after infusion. This is so your doctor can check if your treatment is working and help you if you have any side effects.

If you miss any appointments, call your doctor or the qualified clinical facility as soon as possible to reschedule your appointment.

Driving or using machines

Be careful driving or operating machinery.

Some people may feel tired, dizzy or have some shaking after being given YESCARTA. If this happens to you, do not drive or use heavy machines until at least 8 weeks after infusion or until your doctor tells you that you have completely recovered.

6. Are there any side effects?

Like all medicines, YESCARTA can have side effects, although not everybody gets them. Some may be serious and need medical attention.

YESCARTA can cause side effects to your immune system that may be serious or life-threatening and can lead to death.

Very Serious Side Effects

Very Serious Side Effects	What to do
• Symptoms of cytokine release syndrome such as fever, chills, nausea, diarrhoea, headaches, rapid heartbeat, low blood pressure, dizziness, light headedness, and trouble breathing • Fever, chills, shortness of breath, cough, which may be signs of an infection. • Symptoms of neurologic events such as; loss of consciousness or decreased level of consciousness, confusion or memory loss due to disturbances of brain function, difficulty speaking or slurred speech, involuntary shaking (tremor), fits (seizures), sudden confusion with agitation, disorientation, hallucination or irritability (delirium). • Side effects affecting the heart such as; irregular heartbeat (*arrhythmia*). • Sudden, unexpected stopping of the heart (cardiac arrest); this is serious and life-threatening. • Heart failure. • Blood clots: symptoms can include pain in the chest or upper back, difficulty breathing, coughing up blood or cramping pain, swelling in a single leg, warm and darkened skin around the painful area. • Inability to breathe on one's own (respiratory failure).	**Tell your doctor at the qualified clinical facility immediately or go to the accident and emergency department at the nearest hospital.** **It is important to tell your doctor that you received YESCARTA and to show them your YESCARTA Patient Alert Card.**

Serious Side Effects

Serious Side Effects	What to do
• Blood Test abnormalities: • Decrease in the number of red blood cells (cells that carry oxygen) which may cause you to feel extremely tired with a loss of energy. • Low number of cells that help clot the blood (*thrombocytopenia*); symptoms can include excessive or prolonged bleeding or bruising. • Abnormally low number of white blood cells, which may increase your risk of infections. • Alteration of the blood ability to form clots (coagulopathy): symptoms can include excessive or prolonged bleeding or bruising. • Side effects affecting the gut such as; nausea (feeling sick), constipation, diarrhoea, abdominal pain, vomiting (being sick). • High blood pressure. • Fast heartbeat. • Fluid in the lungs (*pleural effusion*). • Build-up of fluids in tissue (*oedema*) which can lead to swelling, weight gain, difficulty in breathing, and decreased output of urine. • Decreased appetite, weight loss.	**Tell your doctor straight away.**

• Decrease of oxygen reaching body tissues: symptoms can include changes to the colour of your skin, confusion, rapid breathing. • Extreme tiredness. • Lack of energy or strength, muscular weakness, difficulty moving, muscle spasms. • Pain in muscle, joints, bones, arms, hands, legs, back and feet. • Headache. • Infusion reactions such as flushing, rash, itching, fever, alterations in heart rate and blood pressure, shortness of breath or vomiting.	

Less Serious Side Effects

Less Serious Side Effects	What to do

• Loss of control of body movements.
• Nerve pain.
• Dry mouth.
• Loss of movement in muscles of the face.
• Difficulty to swallow
• Blood Test abnormalities:
  ○ Low levels of calcium or albumin
  ○ High levels of bilirubin
  ○ Increase in liver enzymes.
  ○ Low levels of antibodies called immunoglobulins, seen in blood tests, which may lead to infections.
• Anxiety.
• Difficulty Sleeping
• Skin rash or skin problems.
• Dehydration
	Tell your doctor straight away.

Tell your doctor immediately if you get any of the side effects listed above or 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.

7. Product details

This medicine is only used in a qualified treatment centre.

What YESCARTA contains

Active ingredient (main ingredient)	axicabtagene ciloleucel The active substance is axicabtagene ciloleucel. Each patient specific single infusion bag contains a dispersion of anti-CD19 CAR T cells in approximately 68 mL for a target dose of 2 x 10^6 anti-CD19 CAR-positive viable T cells/kg.
Other ingredients (inactive ingredients)	• Cryostor CS10 (contains DMSO) • sodium chloride • human albumin

Your doctor will not give you YESCARTA if you are allergic to any of these ingredients.

What YESCARTA looks like

YESCARTA is a clear to opaque, white to red dispersion for infusion, supplied in an infusion bag individually packed in a metal cassette. A single infusion bag contains approximately 68 mL of cell dispersion.

ARTG No: 329770

ARTG No: 400895

Who distributes YESCARTA

Gilead Sciences Pty Ltd

Level 6, 417 St Kilda Road

Melbourne, Victoria 3004

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