

YESCARTA®

Suspension for Intravenous Infusion (yes-kar-ta)

(*axicabtagene ciloleucel*)

Consumer Medicine Information

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.

What is in this leaflet

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some of the common questions about YESCARTA. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your healthcare professional.

Keep this leaflet handy.

You may need to read it again.

What YESCARTA is used for

How YESCARTA works

YESCARTA is a type of medicine called a “genetically-modified cell therapy”.

YESCARTA is made from your own normal, white blood cells, which have been genetically modified to identify and attack your lymphoma cells.

Lymphoma is a cancer of the blood which affects a type of white blood cell called lymphocytes. The lymphocytes become abnormal causing them to multiply too quickly and live for too long. Too many of these abnormal white blood cells accumulate in your body and this is the cause of the symptoms you may have. YESCARTA is used to treat these conditions when other available medicines have stopped working for you.

Use in children

The use of YESCARTA in children and adolescents under 18 years of age has not yet been studied.

Before you are given YESCARTA

When you must not be given YESCARTA

You should not be given YESCARTA 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.

Before you are given it

Tell your healthcare professional if you have, or have had, any of the following medical conditions:

- have problems with your nervous system (such as fits, stroke, or memory loss).
- have kidney problems.
- have low blood cell levels (blood counts).
- have had a stem cell transplant in the last 4 months.

- have any lung, heart or blood pressure (low or raised) problems.
- 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.

If any of the above apply to you (or you are not sure), talk to your doctor before being 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.

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before being given this medicine.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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.

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.

Do not start any new medicines after being given YESCARTA without first talking with your doctor or pharmacist.

How YESCARTA is given

Test 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.

Medicines and treatments given before YESCARTA infusion

- **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 called 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 YESCARTA is given

- **YESCARTA will always be given to you by a healthcare professional.**
- **YESCARTA is a one-time treatment. It will not be given to you again.**
- **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 will receive YESCARTA infusion in a qualified 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.

If you take too much (overdose)

As YESCARTA 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 YESCARTA, tell your doctor immediately.

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.

Tell your doctor at the certified clinical facility immediately or go to the accident and emergency department at the nearest hospital if you get any of the following side effects:

- Fever
- Difficulty breathing
- Chills or shaking chills
- Confusion
- Dizziness or lightheadedness
- Severe nausea, vomiting, or diarrhoea
- Fast or irregular heartbeat
- Severe fatigue or weakness

It is important to tell your doctor that you received YESCARTA and to show them your YESCARTA Patient Alert Card.

The following side effects have been reported in clinical trials with YESCARTA.

Very common side effects

- Fever, chills, reduced blood pressure which may cause symptoms such as dizziness, lightheadedness, fluid in the lungs, which may be severe and can be fatal (all symptoms of a condition called cytokine release syndrome).
- Fever or chills.
- 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 blood pressure, dizziness.
- Feeling sick, constipation, diarrhoea, pain in the stomach or being sick.
- Headache, depressed level of consciousness, difficulty in speaking, agitation, shaking.
- Decrease in the number of normal white blood cells, which are important for fighting infections.
- Decreased levels of calcium, sodium, phosphate, or potassium which will show up on blood tests.
- Changes in the rhythm or rate of the heartbeat.
- Anxiety
- Decrease in the number of cells that help clot the blood (thrombocytopenia).
- Infections in the blood caused by bacteria, viruses, fungi or other types of infection.
- Shortness of breath, cough.
- Low levels of antibodies called immunoglobulins, which may lead to infections.
- High blood pressure.
- Swelling in the limbs, fluid around the lungs (pleural effusion).
- Muscle pains, back pain.
- Extreme tiredness.
- Dehydration.

Common side effects

- Difficulty understanding numbers, memory loss, fits, loss of control of body movements.
- Failure of the kidneys causing your body to hold onto fluid which can be serious or life threatening.
- Fluid in the lungs.
- Lung infection.
- Sudden, unexpected stopping of the heart (cardiac arrest); this is serious and life-threatening.
- Heart failure.
- Muscle spasms.
- Leakage of fluids from blood vessels into surrounding tissue. This can lead to a weight gain and difficulty in breathing.
- Decreased levels of calcium which will show up on blood tests.
- Infections in the blood caused by fungi.

Tell your doctor immediately if you get any of the side effects listed above. Do not try to treat your symptoms with other medicines on your own.

After you are given YESCARTA

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 certified clinical facility as soon as possible to reschedule your appointment.

Things to be careful of

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.

Product Description

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.

What YESCARTA contains

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 2×10^6 anti-CD19 CAR-positive viable T cells/kg.

The other ingredients (excipients) are:

- Cryostor CS10,
- sodium chloride,
- human albumin.

Sponsor

YESCARTA is supplied in Australia by:

Gilead Sciences Pty Ltd
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