YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

Important Safety Information for Patient, Guardians, and Caregivers

INTRODUCTION

Your doctor will give you a copy of the Patient Alert Card and Patient Educational Guide (this document).

Please read the Patient Educational Guide before you start treatment with YESCARTA® or TECARTUS® to understand the signs and symptoms of cytokine release syndrome and neurological events that require immediate medical attention.

Please carry the Patient Alert Card with you at all times and show it to all healthcare providers who are involved in your medical care.

Talk with your healthcare providers if you have any questions about your health condition or treatment with YESCARTA® or TECARTUS®.

What is the most important information you should know about YESCARTA® and TECARTUS®?

YESCARTA® and TECARTUS® may cause side effects like cytokine release syndrome and neurological problems that are life-threatening and may lead to death. Consult your doctor or seek immediate medical attention if you experience any of the following:

- Fever (38°C or higher)
- Difficulty breathing
- Chills or shaking chills
- Confusion
- Dizziness or lightheadedness
- Severe nausea, vomiting, or diarrhoea
- Fast or irregular heartbeat
- Severe fatigue or weakness
- Decreased level of consciousness
- Seizures
- Tremors

What is YESCARTA® and TECARTUS®?

YESCARTA® and TECARTUS® are cancer medicines that are made from your own white blood cells, which have been modified to recognise and attack your cancer cells.

YESCARTA® is used to treat non-Hodgkin lymphoma, a type of cancer that affects the lymph tissue, which is part of the immune system. This cancer targets a type of white blood cell called B lymphocytes and can also affect other organs in your body. YESCARTA® is prescribed for the following conditions:

- diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) when your first treatment did not work or your cancer returned within 12 months from completion of first treatment, OR
- large B-cell lymphoma (LBCL) when at least two kinds of treatment have failed to control your cancer.

TECARTUS® is used to treat mantle cell lymphoma, when at least two other kinds of treatment have failed to control your cancer. Mantle cell lymphoma is a cancer of a part of the immune system that affects B-lymphocytes. In mantle cell lymphoma, B-lymphocytes grow in an uncontrolled way and build up in the lymph tissue, bone marrow or blood.

Before you are given YESCARTA® or TECARTUS®, tell your healthcare provider about all your medical problems, including:

- Neurologic problems (such as seizures, stroke, or memory loss)
- Lung or breathing problems
- Heart problems
- Liver problems
- Kidney problems
- A recent or active infection

Inform your healthcare provider of all the medications that you are taking,

including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will you receive YESCARTA® or TECARTUS®?

- YESCARTA® or TECARTUS® will always be given to you by a healthcare professional.
- Since YESCARTA® or TECARTUS® is made from your own white blood cells, your blood will be collected by a process called “leukapheresis”, which will concentrate your white blood cells.
- Your blood cells will be sent to a manufacturing centre to make YESCARTA® or TECARTUS®.
- Before you are administered YESCARTA® or TECARTUS®, you will receive 3 days of lymphodepleting chemotherapy (fifth, fourth and third day prior to YESCARTA® or TECARTUS® infusion), which will allow the modified white blood cells in YESCARTA® or TECARTUS® to multiply in your body when the product is given to you.
- When YESCARTA® or TECARTUS® is ready, your doctor will administer it to you through a catheter placed into your vein (intravenous infusion). The infusion is usually completed within 30 minutes.
- You will be monitored daily for at least 7 days after the infusion. Your doctor will recommend that you return to the hospital daily or that you stay at the hospital for the first 7 days after YESCARTA® or TECARTUS® treatment. This is so your doctor can check if your treatment is working and help you if you have any side effects.
- You must stay close to the location (within 2 hours of travel) from where you received your treatment for at least 4 weeks after YESCARTA® or TECARTUS® treatment.
- You may be hospitalised for side effects and your doctor will discharge you if your side effects are under control.
- It is important that you have your blood regularly tested to monitor your progress. If you miss an appointment, call your healthcare provider as soon as possible to reschedule.

What are the possible or likely side effects of YESCARTA® and TECARTUS®?

Tell your doctor immediately if you develop any of the following side effects after YESCARTA® or TECARTUS® infusion:

- High fever (38ºC or higher), chills, extreme tiredness, low blood pressure which may cause symptoms such as dizziness or lightheadedness, shortness of breath, rapid heartbeat or irregular heartbeat. These may be signs of a serious condition known as cytokine release syndrome.
- Loss of consciousness or decreased level of consciousness, confusion and disorientation, fits, involuntary shaking, difficulty speaking or slurred speech, loss of balance or coordination. These may be signs of neurological problems.
- Fever, chills, which may be signs of an infection. Infections can be due to abnormally low number of white blood cells or low level of antibodies called ‘immunoglobulins’ in the blood which help fight infections.

Other possible side effects that may occur with YESCARTA® or TECARTUS® infusion are listed below. If these side effects become severe or serious, tell your doctor immediately.

Very common: may affect more than 1 in 10 people

- Decrease in the number of red blood cells (cells that carry oxygen). Symptoms can include extreme tiredness with a loss of energy.
- Low number of cells that help clot the blood. Symptoms can include excessive or prolonged bleeding or bruising.
- High blood pressure.
- Low levels of sodium, phosphate, potassium or calcium seen in blood tests.
- High levels of uric acid or sugar (glucose) seen in blood tests.
- Decreased appetite, sore mouth.
- Difficulty sleeping, anxiety.
- Cough.
- Nausea, constipation, diarrhoea, abdominal pain, vomiting, difficulty swallowing.
- Increase in liver enzymes seen in blood tests.
- Kidney problems causing your body to hold onto fluid, build-up fluids in tissue (oedema) which can lead to weight gain and difficulty in breathing, decrease output of urine.
- Skin rash or skin problems.
- Muscle and joint pain, back pain.
- Swelling in the limbs, fluid around the lungs.
- 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.
- Nerve pain.

Reporting of side effects

The above listed are not all the possible side effects of YESCARTA® and TECARTUS®. Talk to your doctor if you experience any side effects. YESCARTA® and TECARTUS® may rarely increase your risk of developing cancers including certain types of blood cancers. Your healthcare provider should monitor you for this.

What should you avoid after receiving YESCARTA® or TECARTUS®?

- Do not drive, operate heavy machinery, or participate in any dangerous activities for at least 8 weeks after you receive YESCARTA® or TECARTUS® because the treatment may cause sleepiness, confusion, weakness, and temporary memory and coordination problems.
- Do not donate blood, organs, tissues, or cells for transplantation.

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