YESCARTA®
(axicabtagene ciloleucel) Suspension for IV infusion

Important safety information for patient, guardians, and caregivers

Introduction

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

Please read the Patient Educational Guide before you start treatment with YESCARTA® 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®.

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

YESCARTA® 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®?

YESCARTA® is used to treat large B-cell lymphoma, a type of non-Hodgkin lymphoma. It is used when at least two other kinds of treatment have failed to control your cancer. YESCARTA® is different from other cancer medicines because it is made from your own white blood cells, which have been modified to recognise and attack your lymphoma cells.

Before getting YESCARTA®, 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®?

- Since YESCARTA® 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®.
- Before you are administered YESCARTA®, you will receive 3 days of lymphodepleting chemotherapy (fifth, fourth and third day prior to YESCARTA® infusion) to prepare your body.
- When YESCARTA® 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.
- It is advised to stay close to the location (within 2 hours of travel) from where you received your treatment for at least 4 weeks after getting YESCARTA®. Your doctor will help you with any side effects that may occur.
- 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®?

The most common side effects of YESCARTA® include:

- Fever (38°C or higher)
- Low white blood cells (can occur with a fever)
- Low red blood cells
- Low blood pressure (dizziness or lightheadedness, headache, feeling tired, short of breath)
- Fast heartbeat
- Confusion
- Difficulty speaking or slurred speech
- Nausea
- Diarrhoea

Reporting of side effects

The above listed are not all the possible side effects of YESCARTA®. Talk to your doctor if you experience any side effects.

What should you avoid after receiving YESCARTA®?

- Do not drive, operate heavy machinery, or participate in any dangerous activities for 8 weeks after you receive YESCARTA® 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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