Patient Information Leaflet
YESCARTA (pronounced yes-kar-ta)
(axicabtagene ciloleucel)

Read this Patient Information Leaflet before you start your YESCARTA treatment. The more you know about your treatment, the more active you can be in your care. Talk with your healthcare provider if you have questions about your health condition or treatment. Reading this Patient Information Leaflet does not take the place of talking with your healthcare provider about your treatment.

What is the most important information I should know about YESCARTA?

YESCARTA may cause side effects that are life-threatening and can lead to death. Call or see your healthcare provider or get emergency help right away if you get any of the following:

- Fever (38°C or higher)
- Difficulty breathing
- Chills or shaking chills
- Confusion
- Dizziness or lightheadedness
- Severe nausea, vomiting, or diarrhea
- Fast or irregular heartbeat
- Severe fatigue or weakness

It is important to tell your healthcare provider that you received YESCARTA and to show them your YESCARTA Patient Alert Card. Your healthcare provider may give you other medicines to treat your side effects.

What is YESCARTA?

YESCARTA is a prescription medicine used to treat non-Hodgkin lymphoma:

- 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.

YESCARTA is different than other cancer medicines because it is made from your own white blood cells, which have been modified to recognize and attack your lymphoma cells.

Before getting YESCARTA, tell your healthcare provider about all your medical problems, including if you have or have had:

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

Tell your healthcare provider about all the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive YESCARTA?

- Since YESCARTA is made from your own white blood cells, your blood will be collected by a process called “leukapheresis” (loo-kah-fur-ee-sis), which will concentrate your white blood cells.
- Your blood cells will be sent to a manufacturing center to make your YESCARTA.
- Before you get YESCARTA, you will get 3 days of chemotherapy to prepare your body.

- When your YESCARTA is ready, your healthcare provider will give it to you through a catheter placed into your vein (intravenous infusion). The infusion usually takes less than 30 minutes.
- You will be monitored where you received your treatment daily for at least 7 days after the infusion.
- You should plan to stay close to a certified healthcare facility for at least 4 weeks after getting YESCARTA. Your healthcare provider will help you with any side effects that may occur.
- You may be hospitalized for side effects and your healthcare provider will discharge you if your side effects are under control, and it is safe for you to leave the hospital.
- Your healthcare provider will want to do blood tests to follow your progress. It is important that you do have your blood tested. If you miss an appointment, call your healthcare provider as soon as possible to reschedule.

What should I avoid after receiving YESCARTA?

- Do not drive, operate heavy machinery, or do other dangerous things for 8 weeks after you get YESCARTA because the treatment can cause sleepiness, confusion, weakness, and temporary memory and coordination problems.
- Do not donate blood, organs, tissues, or cells for transplantation.

What are the possible or reasonably 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
- Diarrhea

YESCARTA may increase your risk of getting cancers including certain types of blood cancers. Your healthcare provider should monitor you for this.

These are not all the possible side effects of YESCARTA. Call your healthcare provider about any side effects that concern you.

General information about the safe and effective use of YESCARTA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. If you would like more information about YESCARTA, talk with your healthcare provider. You can ask your healthcare provider for information about YESCARTA that is written for health professionals.

What are the ingredients in YESCARTA?

Active ingredients: axicabtagene ciloleucel. Each single infusion bag of YESCARTA contains a suspension of chimeric antigen receptor (CAR)-positive T cells in approximately 68 mL. The target dose is 2×10^6 CAR-positive viable T cells per kg body weight, with a maximum of 2×10^8 CAR-positive viable T cells.

Inactive ingredients: Cryostor CS10 (contains DMSO), sodium chloride and human albumin.

YESCARTA is a clear to opaque, white to red dispersion for infusion, supplied in an infusion bag individually packed in a metal cassette.

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