



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Yescarta (*axicabtagene ciloleucel*)

An overview of Yescarta and why it is authorised in the EU

### What is Yescarta and what is it used for?

Yescarta is a medicine for treating adults with certain types of blood cancer:

- high-grade B-cell lymphoma (HGBL);
- diffuse large B-cell lymphoma (DLBCL);
- primary mediastinal large B-cell lymphoma (PMBCL);
- follicular lymphoma (FL).

Yescarta is for use in patients whose blood cancer has returned (recurrent) or has stopped responding to previous treatment (refractory).

Yescarta is a type of advanced therapy medicine called a 'gene therapy product'. This is a type of medicine that works by delivering genes into the body.

The blood cancers that Yescarta is used to treat are rare, and Yescarta was designated an 'orphan medicine' (a medicine used in rare diseases) for DLBCL on [16 December 2014](#), for PMBCL on [9 October 2015](#) and for FL on [11 November 2015](#).

Yescarta contains the active substance axicabtagene ciloleucel (consisting of genetically modified white blood cells).

### How is Yescarta used?

Yescarta is prepared using the patient's own white blood cells which are extracted from the blood, genetically modified in the laboratory, and then given back to the patient.

It is given as a single infusion (drip) into a vein and must only be given to the patient whose cells were used to make it. Before having Yescarta, the patient should have a short course of chemotherapy to clear away their existing white blood cells, and just before the infusion they should be given paracetamol and an antihistamine medicine to reduce the risk of reactions to the infusion.

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A medicine called tocilizumab (or a suitable alternative if this is unavailable due to a shortage) and emergency equipment must be available in case the patient has a potentially serious side effect called cytokine release syndrome (see risks section below).

Patients should be closely monitored for 10 days after treatment for side effects and are advised to stay close to a specialist hospital for at least 4 weeks after treatment.

For more information about using Yescarta, see the package leaflet or contact your doctor or pharmacist.

## **How does Yescarta work?**

Yescarta contains the patient's own T cells (a type of white blood cell) that have been modified genetically in the laboratory so that they make a protein called chimeric antigen receptor (CAR). CAR can attach to another protein on the surface of cancer cells called CD19.

When Yescarta is given to the patient, the modified T cells attach to cancer cells and kill them, thereby helping to clear the cancer from the body.

## **What benefits of Yescarta have been shown in studies?**

### **High-grade B-cell lymphoma (HGBL) and diffuse large B-cell lymphoma (DLBCL) after one line of treatment**

A main study involving 359 patients with HGBL or DLBCL that had not responded to, or returned within a year of receiving one previous treatment, showed that Yescarta is effective at prolonging the time patients live without experiencing a certain event (worsening of disease, start of a new lymphoma therapy, or death). On average, patients given Yescarta were event-free for around 8 months, compared with 2 months for patients given standard cancer treatments. In addition, 41% of patients given Yescarta were event-free after 24 months of treatment, compared with 16% of patients receiving standard treatment.

### **Diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL) after two or more lines of treatment**

A main study of 111 patients with DLBCL and PMBCL that was not responding to two previous treatments or had returned showed that Yescarta is effective at clearing the cancer in many patients. Of the patients who joined the study, 47% had a complete response (which means they had no signs of the cancer left) and 66% had at least a partial response after treatment with Yescarta.

These results were better than those from studies of patients receiving standard cancer treatments, where around 7% of patients had a complete response and around 26% had at least a partial response.

### **Follicular lymphoma (FL) after three or more lines of treatment**

A main study of 75 patients with FL that, after at least three previous treatments, was not responding or had returned showed that Yescarta is effective at clearing the cancer in many patients. Of these, 91% responded to the treatment, with 77% having a complete response.

These results were better than those seen in studies with patients receiving standard treatments for FL.

## **What are the risks associated with Yescarta?**

Serious side effects may occur in about 1 in 2 patients. The most common serious side effects are cytokine release syndrome (a potentially life-threatening condition that can cause fever, vomiting, shortness of breath, pain and low blood pressure), encephalopathy (a brain disorder associated with headache, sleepiness and mental confusion) and infections.

Yescarta must not be used in patients allergic to gentamicin (a type of antibiotic). For the full list of side effects and restrictions with Yescarta, see the package leaflet.

## **Why is Yescarta authorised in the EU?**

A main study showed that Yescarta is effective at clearing the cancer in many patients with DLBCL, HGBL and PMBCL that was not responding to previous treatment or had returned. The number of patients who were cleared of the cancer or had at least a partial response was higher than in patients receiving standard care. Another study also showed that the medicine is effective at clearing the cancer in many patients with FL that, after at least three previous treatments, was not responding or had returned.

Serious side effects, particularly cytokine release syndrome, are common in patients being treated with Yescarta; however these are manageable if appropriate measures are in place (see below). The European Medicines Agency therefore decided that Yescarta's benefits are greater than its risks and it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Yescarta?**

The company that markets Yescarta must ensure that hospitals where Yescarta is given have appropriate expertise, facilities and training. Tocilizumab or a suitable alternative must be available in case of cytokine release syndrome. The company must provide educational materials for healthcare professionals and patients about possible side effects, especially cytokine release syndrome.

The company must also carry out a study to obtain more information on the long term safety of Yescarta.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Yescarta have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Yescarta are continuously monitored. Side effects reported with Yescarta are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Yescarta**

Yescarta received a marketing authorisation valid throughout the EU on 23 August 2018.

Further information on Yescarta can be found on the Agency's website:

[ema.europa.eu/en/medicines/human/EPAR/yescarta](https://ema.europa.eu/en/medicines/human/EPAR/yescarta).

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