Yescarta® ▼ (axicabtagene ciloleucel) Dispersion for infusion
Tecartus® ▼ (brexucabtagene autoleucel) Dispersion for infusion

IMPORTANT SAFETY INFORMATION FOR HEALTHCARE PROFESSIONALS FOR THE RISKS OF:

- CYTOKINE RELEASE SYNDROME
- SERIOUS NEUROLOGIC ADVERSE REACTIONS
- SECONDARY MALIGNANCY OF T-CELL ORIGIN

Yescarta (axicabtagene ciloleucel) is indicated for the treatment of the following:

- Adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy.
- Adult patients with relapsed or refractory DLBCL and primary mediastinal large B-cell lymphoma (PMBCL), after two or more lines of systemic therapy.
- Adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic therapy.

Tecartus (brexucabtagene autoleucel) is indicated for the treatment of the following:

- Adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor
- Adult patients 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL).

▼THESE MEDICINAL PRODUCTS ARE SUBJECT TO ADDITIONAL MONITORING. THIS WILL ALLOW QUICK IDENTIFICATION OF NEW SAFETY INFORMATION. HEALTHCARE PROFESSIONALS ARE ASKED TO REPORT ANY SUSPECTED ADVERSE REACTIONS.

The risk minimisation materials fulfil the conditions of the marketing authorisation and have been approved by the competent authority in July 2026 in accordance with GVP Module XVI.

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LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

ALL	Acute lymphoblastic leukaemia
BTK	Bruton's tyrosine kinase
CNS	Central nervous system
CRS	Cytokine release syndrome
DLBCL	Diffuse large B-cell lymphoma
FL	Follicular lymphoma
HCP	Healthcare professional
HGBL	High-grade B-cell lymphoma
HLH/MAS	Haemophagocytic lymphohistiocytosis/macrophage activation syndrome
HPRA	Health products regulatory authority
ICANS	Immune effector cell-associated neurotoxicity syndrome
MCL	Mantle cell lymphoma
PMBCL	Primary mediastinal large B-cell lymphoma
SmPC	Summary of Product Characteristics

1. INDICATIONS

Yescarta (axicabtagene ciloleucel) is indicated for the treatment of the following:

- Adult patients with diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) that relapses within 12 months from completion of, or is refractory to, first-line chemoimmunotherapy.
- Adult patients with relapsed or refractory DLBCL and primary mediastinal large B-cell lymphoma (PMBCL), after two or more lines of systemic therapy.
- Adult patients with relapsed or refractory follicular lymphoma (FL) after three or more lines of systemic therapy.

Tecartus (brexucabtagene autoleucel) is indicated for the treatment of:

- Adult patients with relapsed or refractory mantle cell lymphoma (MCL) after two or more lines of systemic therapy including a Bruton's tyrosine kinase (BTK) inhibitor
- Adult patients 26 years of age and above with relapsed or refractory B-cell precursor acute lymphoblastic leukaemia (ALL).

The European Commission approved Yescarta (axicabtagene ciloleucel) and Tecartus (brexucabtagene autoleucel) with additional risk minimisation measures to ensure that the benefits outweigh the risks. Administration of Yescarta or Tecartus can result in severe, life-threatening, and fatal reactions like cytokine release syndrome (CRS) and serious neurologic adverse reactions, also known as immune effector cell-associated neurotoxicity syndrome (ICANS).

Yescarta (axicabtagene ciloleucel) and Tecartus (brexucabtagene autoleucel), hereafter referred to as Kite cellular therapy products, will only be supplied to hospitals and associated centres that are qualified and only if the healthcare professionals (HCPs) involved in the treatment of a patient have completed training on the HCP educational material, and have on-site, immediate access to tocilizumab. In the exceptional case where tocilizumab is not available due to a shortage that is listed in the European Medicines Agency shortage catalogue, ensure that suitable alternative measures to treat CRS are available on site.

To mitigate the safety risks associated with these two Kite cellular therapy products, treatment centres must be specifically qualified prior to ordering either product.

2. PURPOSE OF THE EDUCATIONAL MATERIAL FOR YESCARTA OR TECARTUS

This guide is intended to provide information on serious adverse reactions of CRS and serious neurologic adverse reactions/ICANS associated with the use of either of these two Kite cellular therapy products, including guidance on monitoring for CRS and neurologic adverse reactions and reporting of any adverse reactions. In addition, patients treated with these two Kite cellular therapy products may develop secondary malignancies of T-cell origin and, therefore, should be monitored life-long. This guide will provide information on the appropriate samples that can be sent for further investigation. These samples will be used to test whether the T-cell malignancy is due to insertional mutagenesis resulting from treatment with Kite cellular therapy products.

The educational material will help HCPs in identifying patients with CRS and serious neurologic adverse reactions/ICANS and direct them to the appropriate guidelines for managing these events. HCPs are asked to report any suspected adverse reactions. All patients or their caregivers must be given a Patient Card by their HCP to educate them about the symptoms of CRS and serious neurologic adverse reactions/ICANS and the need to report the symptoms to their treating doctor immediately. Treating HCPs should also advise their patients to keep the Patient Card with them at all times and show it to any HCP who may treat them.

Review the full Summary of Product Characteristics (SmPCs) and the Patient Information Leaflets for Yescarta and/or Tecartus for a more detailed description of the other risks and adverse reactions.

Read this HCP Educational Material prior to prescribing Yescarta and/or Tecartus. This will enable you to:

- Identify patients with CRS and serious neurologic adverse reactions/ICANS and learn the importance of excluding alternate causes
- Utilise the Patient Card with patients
- Ensure that adverse reactions are adequately and appropriately reported
- Ensure patients are monitored life-long for T-cell malignancies, and if a malignancy of T-cell origin occurs, the need to contact Kite to discuss appropriate patient samples to send for further testing

The information in this guide is provided by Kite, a Gilead Company, (hereafter referred to as Kite) for HCPs who are involved in the treatment of patients who receive either of the two Kite cellular therapy products. To obtain copies of the Patient Card, contact Kite Medical Information at UKMed.Info@gilead.com or by telephone on +353 214825999. Also, see the Yescarta and/or Tecartus SmPCs for more information.

These medicinal products are subject to additional monitoring. This will allow quick identification of new safety information. To report an adverse reaction associated with either of these two Kite cellular therapy products, please email Safety_FC@gilead.com or telephone +44 (0) 1223 897500.

3. WHAT IS YESCARTA OR TECARTUS

Yescarta and Tecartus are engineered autologous T-cell immunotherapy products that bind to CD19-expressing cancer cells and normal B cells. Following anti-CD19 chimeric antigen receptor T-cell engagement with CD19-expressing target cells, the CD28 co-stimulatory domains and CD3-zeta signaling domain activate downstream signaling cascades that lead to T-cell activation, proliferation, acquisition of effector functions, and secretion of inflammatory cytokines and chemokines. This sequence of events leads to apoptosis and necrosis of CD19-expressing target cells.

4. IMPORTANT POINTS TO CONSIDER BEFORE YOU ADMINISTER YESCARTA OR TECARTUS

To mitigate the safety risks associated with these two Kite cellular therapy products, treatment centres must be specifically qualified prior to ordering Yescarta or Tecartus. As a part of the qualification process, HCPs will be trained on the Educational Materials; the treatment centre is responsible for ensuring training of appropriate personnel.

These two Kite cellular therapy products must be administered in a qualified clinical setting. At least 1 dose per patient of tocilizumab, an interleukin-6 (IL-6) receptor inhibitor, must be on site and available for administration prior to Yescarta or Tecartus infusion. The qualified treatment centre must have access to an additional dose of tocilizumab within 8 hours of each previous dose. In the exceptional case where tocilizumab is not available due to a shortage that is listed in the European Medicines Agency shortage catalogue, the treatment centre must have access to suitable alternative measures instead of tocilizumab to treat CRS.

Patients must be monitored daily for the first 7 days following Yescarta or Tecartus infusion for signs and symptoms of potential CRS, neurologic events and other toxicities. Physicians can consider hospitalisation for the first 7 days or at the first signs or symptoms of CRS and/or neurologic events. After the first 7 days following the Yescarta or Tecartus infusion, the patient is to be monitored at the physician's discretion for at least an additional 7 days.

Patients must remain within proximity of a qualified treatment centre or an appropriately trained clinical facility for at least 2 weeks following infusion.

The European Society for Blood and Marrow Transplantation is maintaining a registry for follow-up of patients who received Yescarta or Tecartus. Additional information can be obtained from: **registryhelpdesk@ebmt.org**

- The aim of the registry is to collect long-term data for Yescarta and Tecartus. Such data is important to further understand the benefit/risk for these products.
- The inclusion of data in the registry does not replace the obligation to spontaneously report adverse events through **Safety_FC@gilead.com** or telephone + 353 (0) 214 825 999 or the Health Products Regulatory Authority (HPRA) via HPRA Pharmacovigilance, website **www.hpra.ie**.

Due to the risks associated with these two Kite cellular therapy products, infusion must be delayed if a patient has any of the following conditions:

- Unresolved serious adverse reactions (especially pulmonary reactions, cardiac reactions or hypotension) including from preceding chemotherapies.
- Active uncontrolled infection or inflammatory disease.
- Active graft-versus-host disease.

Yescarta or Tecartus must not be administered until these conditions have been resolved.

5. GUIDANCE ON MANAGING CYTOKINE RELEASE SYNDROME

Table 1 outlines the signs and symptoms associated with CRS.

Table 1. Signs and Symptoms Associated With CRS

CRS	
Any organ can be affected by CRS. The following are common signs and symptoms:	
Pyrexia	Chills
Fatigue	Renal impairment
Cardiac failure	Headache
Tachycardia	Malaise
Cardiac arrhythmias	Transaminitis
Dyspnoea	Nausea
Hypoxia	Diarrhoea
Capillary leak syndrome	Hypotension
Cardiac arrest	Tachypnoea

Abbreviations: CRS = cytokine release syndrome

Yescarta

The safety data described below are from a total of 397 adult patients treated with Yescarta in three multi-centre pivotal clinical studies (ZUMA-1 which treated 108 patients with DLBCL or PMBCL indication; ZUMA-5 which treated 119 patients with FL indication; and ZUMA-7 which treated 170 patients with DLBCL or HGBL indication). Table 2 summarizes the CRS incidence, time to onset and duration for Yescarta.

Table 2. Yescarta CRS Incidence, Time to Onset and Duration

Study	CRS incidence	CRS ≥ Grade 3 incidence	Median time to onset	Median duration
ZUMA-1 and ZUMA-7	92%	8%	3 days (range: 1 to 12 days)	7 days (range: 2 to 58 days)
ZUMA-5	77%	6%	4 days (range: 1 to 11 days)	6 days (range: 1 to 27 days)

In ZUMA-1, ZUMA-5 and ZUMA-7, 99% of patients recovered from CRS.

Serious adverse reactions that may be associated with CRS included pyrexia (12%), hypotension (5%), hypoxia (3%), arrhythmia (3%), cardiac failure (2%), fatigue (2%), headache (2%), tachycardia (2%), cardiac arrest (1%), dyspnoea (1%), and tachypnoea (1%).

Tecartus

The safety data described below are from a total of 182 adult patients treated with Tecartus in two multi-centre pivotal clinical studies (ZUMA-2 which treated 82 patients with MCL indication and ZUMA-3 which treated 100 patients with ALL indication). Table 3 summarizes the CRS incidence, time to onset and duration for Tecartus.

Table 3. Tecartus CRS Incidence, Time to Onset and Duration

Study	CRS incidence	CRS ≥ Grade 3 incidence	Median time to onset	Median duration
ZUMA-2 and ZUMA-3	91%	20%	3 days (range: 1 to 13 days)	9 days (range: 1 to 63 days)

Ninety-seven percent (97%) of patients recovered from CRS. Serious adverse reactions that may be associated with CRS included hypotension (22%), pyrexia (15%), hypoxia (9%), tachycardia (3%), dyspnoea (2%) and sinus tachycardia (2%).

Yescarta and Tecartus

Infusion of these two Kite cellular therapy products must be delayed if a patient has active uncontrolled infection or inflammatory disease until these conditions have resolved. Diagnosis of CRS requires excluding alternative causes of systemic inflammatory response, including infection. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids and other supportive care as medically indicated.

CRS has been known to be associated with end organ dysfunction (e.g., hepatic, renal, cardiac, and pulmonary). In addition, worsening of underlying organ pathologies can occur in the setting of CRS. Patients with medically significant cardiac dysfunction must be managed by standards of critical care and measures such as echocardiography must be considered. Evaluation for HLH/MAS is to be considered in patients with severe or unresponsive CRS.

The management of patients should be conducted based on the patient's clinical presentation and in accordance with applicable local institutional and/or national or European/international clinical guidelines. Physicians are advised to exercise clinical judgment consistent with these standards.

Yescarta and Tecartus continue to expand and persist following administration of tocilizumab and corticosteroids. Tumour necrosis factor antagonists are not recommended for management of CRS associated with these two Kite cellular therapy products.

6. GUIDANCE ON MANAGING NEUROLOGIC ADVERSE REACTIONS

Table 4 outlines the signs and symptoms associated with neurologic adverse reactions.

Table 4. Signs and Symptoms Associated with Neurologic Adverse Reactions

NEUROLOGIC ADVERSE REACTIONS	
The following are common signs and symptoms:	
Seizures	Ataxia
Somnolence	Memory impairment
Headache	Mental status changes
Confusion	Hallucinations
Agitation	Depressed level of consciousness
Speech disorders	Delirium
Tremor	Dysmetria
Encephalopathy	

Yescarta

Table 5 summarizes the Yescarta neurologic adverse reactions; the data described below are from a total of 397 adult patients treated with Yescarta in three multi-centre pivotal clinical studies (ZUMA-1 which treated 108 patients with DLBCL or PMBCL indication; ZUMA-5 which treated 119 patients with FL indication; and ZUMA-7 which treated 170 patients with DLBCL or HGBL indication).

Table 5. Yescarta Neurologic Adverse Reactions: Incidence, Time to Onset and Duration

Study	Neurologic adverse reactions incidence	Neurologic adverse reactions ≥ Grade 3 incidence	Median time to onset	Median duration
ZUMA-1 and ZUMA-7	63%	25%	6 days (range: 1 to 133 days)	10 days
ZUMA-5	57%	16%	7 days (range: 1 to 177 days)	14 days

In ZUMA-1 and ZUMA-7, neurologic adverse reactions occurred in 63% of patients. Twenty-five percent (25%) of patients experienced Grade 3 or higher (severe or life-threatening) adverse reactions. Neurologic toxicities occurred within the first 7 days of infusion for 75% of patients. The median time to onset was 6 days (range: 1 to 133 days). The median duration was 10 days, with resolution occurring within 3 weeks for 66% of patients following infusion.

In ZUMA-5, neurologic adverse reactions occurred in 57% of patients. Sixteen percent (16%) of patients experienced Grade 3 or higher (severe or life-threatening) adverse reactions. Neurologic toxicities occurred within the first 7 days of infusion for 65% of patients. The median time to onset was 7 days (range: 1 to 177 days). The median duration was 14 days, with resolution occurring within 3 weeks for 60% of patients following infusion.

The most common (≥5%) neurologic adverse reactions included encephalopathy (51%), tremor (28%), and delirium (14%). Serious neurologic adverse reactions reported in patients included encephalopathy (18%), tremor (2%), delirium (2%), hemiparesis (1%) and seizure (1%).

Other neurologic adverse reactions have been reported less frequently in clinical trials and included dysphagia (3%), myelitis (0.2%), and quadriplegia (0.2%).

Adverse reactions reported in the post-marketing setting include status epilepticus (0.3%), spinal cord oedema and ICANS.

Tecartus

Table 6 summarizes the Tecartus neurologic adverse reactions; the data described below are from a total of 182 adult patients treated with Tecartus in two multi-centre pivotal clinical studies (ZUMA-2 which treated 82 patients with MCL indication and ZUMA-3 which treated 100 patients with ALL indication).

Table 6. Tecartus Neurologic Adverse Reactions Incidence, Time to Onset and Duration

Study	Neurologic events incidence	Neurologic events ≥ Grade 3 incidence	Median time to onset	Median duration
ZUMA-2 and ZUMA-3	69%	32%	7 days (range: 1 to 262 days)	12 days (range: 1 to 708 days)

Neurologic adverse reactions occurred in 69% of patients. Thirty-two percent (32%) of patients experienced Grade 3 or higher (severe or life threatening) adverse reactions. The median time to onset was 7 days (range: 1 to 262 days). Neurologic events resolved for 113 out of 125 patients (90.4%) with a median duration of 12 days (range: 1 to 708 days). Three patients had ongoing neurologic events at the time of death, including one patient with the reported event of serious encephalopathy and another patient with the reported event of serious confusional state. The remaining unresolved neurologic events were Grade 2. Ninety-three (93%) percent of all treated patients experienced the first CRS or neurological event within the first 7 days after Tecartus infusion.

The most common neurologic adverse reactions that have been reported in patients administered Tecartus included tremor (32%), confusional state (27%), encephalopathy (27%), aphasia (21%) and agitation (11%). ICANS was reported as a serious adverse neurologic reaction at a low frequency (2%) in clinical trials. ICANS observed during clinical studies are represented under the adverse reaction encephalopathy. Serious cases of cerebral oedema which may become fatal have occurred in patients treated with Tecartus.

ICANS was reported in the context of neurologic toxicity in the post marketing setting.

Yescarta and Tecartus

There is limited experience with Yescarta and Tecartus in patients with lymphomas involving the central nervous system (CNS). Patients with a history of CNS disorders such as seizures or cerebrovascular ischaemia may be at increased risk.

The management of patients should be conducted based on the patient's clinical presentation and in accordance with applicable local institutional and/or national or European/international clinical guidelines. Physicians are advised to exercise clinical judgement consistent with these standards.

7. POST YESCARTA OR TECARTUS INFUSION MONITORING

Post Yescarta or Tecartus infusion recommendations:

- Patients must be monitored daily for the first 7 days following infusion for signs and symptoms of potential CRS, neurologic events and other toxicities.
- Physicians can consider hospitalisation for the first 7 days or at the first signs or symptoms of CRS and/or neurologic events.
- After the first 7 days following the infusion, the patient is to be monitored at the physician's discretion for at least an additional 7 days.
- Before discharging the patient, the physician must provide adequate education and counselling to the patient and family/caregiver on the signs and symptoms of CRS and neurologic adverse reactions to ensure their ability to identify them promptly (see Section 8 about patient counselling).
- Patients must remain within proximity of a qualified treatment centre or an appropriately trained clinical facility for at least 2 weeks following infusion so that they can be monitored for signs and symptoms of CRS and neurologic adverse reactions.
- If the patients develop any signs or symptoms of CRS or neurologic adverse reactions, they should be instructed to immediately go to the qualified treatment centre (or nearest hospital if travel is deemed unsafe) for evaluation for hospitalisation and treatment which includes supportive care and use of tocilizumab and/or corticosteroids.

The treating healthcare professional must complete the Patient Card including the name of the product infused.

Below is a checklist of some of the signs and symptoms that the HCP should assess for during weekly calls to the patient. This checklist is not meant to be all-inclusive. Based on the responses below, the decision to bring the patient for evaluation will be at the discretion of the treating physician.

GENERAL	YES	NO
Do you have a fever?		
Do you have any chills?		
Do you have any nausea or vomiting?		
Are you having difficulty sleeping?		
Are you having problems staying awake?		
Are you lightheaded or experiencing dizziness?		
Do you have headaches?		
Do you have loss of balance or coordination?		
Do you have difficulty in speaking or slurred speech?		
Do you have confusion or disorientation?		
Do you have any unusual body movements?		
Do you have dizziness when you stand up?		
Do you have difficulty understanding numbers or doing maths?		
Do you have difficulty writing?		
Do you have shortness of breath or rapid breathing?		
Are you having difficulty breathing?		
Do you have palpitations?		
Are you more tired than you were before the Yescarta or Tecartus infusion?		

8. PATIENT COUNSELLING

Talk to the patient about the risk of CRS and neurologic adverse reactions. Early diagnosis and appropriate management of CRS and neurologic adverse reactions are essential to minimise life-threatening complications. Remind the patient not to treat their own symptoms. Instruct patients to contact their HCP and/or seek immediate care if they experience any signs and symptoms associated with CRS and/or neurologic adverse reactions, which include:

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

Provide the Yescarta and Tecartus Patient Card to the patient or the patient's caregiver. Tell the patient to carry the Patient Card at all times and to share the Patient Card with any HCP involved in the patient's treatment.

After Yescarta or Tecartus infusion patients must remain within proximity of a qualified treatment centre or an appropriately trained clinical facility for a minimum of 2 weeks to monitor for signs and symptoms of CRS or neurologic adverse reactions.

9. FOLLOW-UP ON THE RISK OF SECONDARY MALIGNANCY OF T-CELL ORIGIN

Patients treated with Kite cellular therapy products may develop secondary malignancies of T-cell origin, potentially due to insertional mutagenesis and should be monitored life-long.

If a malignancy of T-cell origin occurs, Kite should be contacted to obtain instructions on how patient samples should be sent for testing. Please contact **UK.Med.Info@gilead.com** or by telephone on +44 (0) 8000 113700.

Kite will provide you with information and guidance regarding the patient's informed consent and what information may be requested from you (e.g., medical history, treatment outcome, prior and current molecular analyses, histopathology, cytogenetic, and/or flow cytometric reports).

The patient samples can include the following:

- blood (peripheral blood mononuclear cells),
- formalin-fixed paraffin-embedded tumour biopsy,
- bone marrow aspirate,
- formalin-fixed paraffin-embedded bone marrow biopsy,
- DNA extracted from blood, tumor biopsy, or bone marrow aspirate/biopsies.

These samples will be used to test whether the T-cell malignancy is due to insertional mutagenesis resulting from treatment with Kite cellular therapy products.

10. REPORTING OF ADVERSE REACTIONS

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit–risk balance of the medicinal product.

HCPs are asked to report any suspected adverse reactions associated with Yescarta or Tecartus to the Marketing Authorisation Holder Kite Pharma EU B.V., (reporting email address: **Safety_FC@gilead.com**) a Gilead company, or the Health Products Regulatory Authority (HPRA) via HPRA Pharmacovigilance, website: **www.hpra.ie** in addition to any recording of data in the Cell Therapy Registry.

Any suspected adverse reactions to Yescarta or Tecartus should be reported to Gilead via email to **Safety_FC@gilead.com**, via the **www.gilead.com** website using the 'Report an Adverse Event' link or by telephone + 353 (0) 21 482 5999.

When reporting a suspected adverse reaction, please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment date.

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