HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TECARTUS safely and effectively. See full prescribing information for TECARTUS.

TECARTUS™ (brexucabtagene autoleucel) suspension for intravenous infusion
Initial U.S. Approval: 2020

WARNING: CYTOKINE RELEASE SYNDROME AND NEUROLOGIC TOXICITIES
See full prescribing information for complete boxed warning.

- **Cytokine Release Syndrome (CRS), including life-threatening reactions, occurred in patients receiving TECARTUS. Do not administer TECARTUS to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids (2.2, 2.3, 5.1).**
- **Neurologic toxicities, including life-threatening reactions, occurred in patients receiving TECARTUS, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with TECARTUS. Provide supportive care and/or corticosteroids, as needed (2.2, 2.3, 5.2).**
- **TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program (5.3).**

----------INDICATIONS AND USAGE----------
TECARTUS is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

----------DOSAGE AND ADMINISTRATION----------
For autologous use only. For intravenous use only.

- Do NOT use a leukodepleting filter.
- Administer a lymphodepleting regimen of cyclophosphamide and fludarabine before infusion of TECARTUS. (2.2)
- Verify the patient's identity prior to infusion. (2.2)
- Premedicate with acetaminophen and diphenhydramine. (2.2)
- Confirm availability of tocilizumab prior to infusion. (2.1, 5.1)
- Dosing of TECARTUS is based on the number of chimeric antigen receptor (CAR)-positive viable T cells. (2.1)
- The TECARTUS 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. (2.1)

Administer TECARTUS in a certified healthcare facility. (2.2, 5.1, 5.2, 5.3)

----------DOSAGE FORMS AND STRENGTHS----------

- TECARTUS is available as a cell suspension for infusion.
- TECARTUS comprises a suspension of 2×10^6 CAR-positive viable T cells per kg of body weight, with a maximum of 2×10^8 CAR-positive viable T cells in approximately 68 mL. (3)

----------CONTRAINDICATIONS----------

- None. (4)

----------WARNINGS AND PRECAUTIONS----------

- Hypersensitivity Reactions: Monitor for hypersensitivity reactions during infusion. (5.4)
- Severe Infections: Monitor patients for signs and symptoms of infection; treat appropriately. (5.5)
- Prolonged Cytopenias: Patients may exhibit Grade 3 or higher cytopenias for several weeks following TECARTUS infusion. Monitor complete blood counts. (5.6)
- Hypogammaglobulinemia: Monitor and provide replacement therapy. (5.7)
- Secondary Malignancies: In the event that a secondary malignancy occurs after treatment with TECARTUS, contact Kite at 1-844-454-KITE (5483). (5.8)
- Effects on Ability to Drive and Use Machines: Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, for at least 8 weeks after receiving TECARTUS. (5.9)

----------ADVERSE REACTIONS----------
The most common non-laboratory adverse reactions (incidence greater than or equal to 20%) are: pyrexia, CRS, hypotension, encephalopathy, fatigue, tachycardia, arrhythmia, infection – pathogen unspecified, chills, hypoxia, cough, tremor, musculoskeletal pain, headache, nausea, edema, motor dysfunction, constipation, diarrhea, decreased appetite, dyspnea, rash, insomnia, pleural effusion, and aphasia. (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Kite at 1-844-454-KITE (5483) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 07/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITIES

- **Cytokine Release Syndrome (CRS), including life-threatening reactions, occurred in patients receiving TECARTUS. Do not administer TECARTUS to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids *[see Dosage and Administration (2.2, 2.3), Warnings and Precautions (5.1)]*.**
- **Neurologic toxicities, including life-threatening reactions, occurred in patients receiving TECARTUS, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with TECARTUS. Provide supportive care and/or corticosteroids as needed *[see Dosage and Administration (2.2, 2.3), Warnings and Precautions (5.2)]*.**
- **TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program *[see Warnings and Precautions (5.3)]*.**

1 INDICATIONS AND USAGE

TECARTUS is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

This indication is approved under accelerated approval based on overall response rate and durability of response[*see Clinical Studies (14)]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 DOSAGE AND ADMINISTRATION

For autologous use only. For intravenous use only.

2.1 Dose

Each single infusion bag of TECARTUS contains a suspension of chimeric antigen receptor (CAR)-positive T cells in approximately 68 mL. The 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.

2.2 Administration

TECARTUS is for autologous use only. The patient's identity must match the patient identifiers on the TECARTUS cassette and infusion bag. Do not infuse TECARTUS if the information on the patient-specific label does not match the intended patient.

Preparing Patient for TECARTUS Infusion

Confirm availability of TECARTUS prior to starting the lymphodepleting chemotherapy regimen.

Pre-treatment

- Administer a lymphodepleting chemotherapy regimen of cyclophosphamide 500 mg/m^2 intravenously and fludarabine 30 mg/m^2 intravenously on each of the fifth, fourth, and third days before infusion of TECARTUS.

Premedication

- Premedicate with acetaminophen and diphenhydramine or another H1-antihistamine approximately 30 to 60 minutes prior to TECARTUS infusion.
- Avoid prophylactic use of systemic corticosteroids as it may interfere with the activity of TECARTUS.

Preparation of TECARTUS for infusion

Coordinate the timing of TECARTUS thaw and infusion. Confirm the infusion time in advance, and adjust the start time of TECARTUS thaw such that TECARTUS will be available for infusion when the patient is ready.

- Confirm patient identity: Prior to TECARTUS preparation, match the patient's identity with the patient identifiers on the TECARTUS cassette.
- Do not remove the TECARTUS infusion bag from the cassette if the patient information on the cassette label does not match the intended patient.
- Once patient identity is confirmed, remove the TECARTUS infusion bag from the cassette and check that the patient information on the cassette label matches the patient information on the bag label.
- Inspect the infusion bag for any breaches of container integrity such as breaks or cracks before thawing. If the bag is compromised, follow the local guidelines (or call Kite at 1-844-454-KITE).
- Place the infusion bag inside a second sterile bag per local guidelines.
- Thaw the infusion bag at approximately 37°C using either a water bath or dry-thaw method until there is no visible ice in the infusion bag.
- Gently mix the contents of the bag to disperse clumps of cellular material. If visible cell clumps remain, continue to gently mix the contents of the bag. Small clumps of cellular material should disperse with gentle manual mixing. Do not wash, spin down, and/or re-suspend TECARTUS in new media prior to infusion.
- Once thawed, TECARTUS should be administered within 30 minutes but may be stored at room temperature (20°C to 25°C) for up to three hours.

Administration

- For autologous use only.
- Ensure that tocilizumab and emergency equipment are available prior to infusion and during the recovery period.
- Do NOT use a leukodepleting filter.
- Central venous access is recommended for the administration of TECARTUS.
- Confirm that the patient's identity matches the patient identifiers on the TECARTUS infusion bag.
- Prime the tubing with normal saline prior to infusion.
- Infuse the entire contents of the TECARTUS bag within 30 minutes by either gravity or a peristaltic pump. TECARTUS is stable at room temperature for up to three hours after thaw.
- Gently agitate the TECARTUS bag during infusion to prevent cell clumping.
- After the entire contents of the TECARTUS bag are infused, rinse the tubing with normal saline at the same infusion rate to ensure all product is delivered.

TECARTUS contains human blood cells that are genetically modified with replication-incompetent retroviral vector. Follow universal precautions and local biosafety guidelines for handling and disposal of TECARTUS to avoid potential transmission of infectious diseases.

Monitoring

- Administer TECARTUS at a certified healthcare facility.
- Monitor patients at the certified healthcare facility daily for at least seven days following infusion for signs and symptoms of Cytokine Release Syndrome (CRS) and neurologic events.
- Instruct patients to remain within proximity of the certified healthcare facility for at least four weeks following infusion.

2.3 Management of Severe Adverse Reactions

Cytokine Release Syndrome

Identify CRS based on clinical presentation *[see Warnings and Precautions (5.1)]*. Evaluate for and treat other causes of fever, hypoxia, and hypotension. If CRS is suspected, manage according to the recommendations in Table 1. Patients who experience Grade 2 or higher CRS (e.g., hypotension, not responsive to fluids, or hypoxia requiring supplemental oxygenation) should be monitored with continuous cardiac telemetry and pulse oximetry. For patients experiencing severe CRS, consider performing an echocardiogram to assess cardiac function. For severe or life-threatening CRS, consider intensive care supportive therapy.

Table 1. CRS Grading and Management Guidance

CRS Grade[a]	Tocilizumab	Corticosteroids
Grade 1 Symptoms require symptomatic treatment only (e.g., fever, nausea, fatigue, headache, myalgia, malaise).	If not improving after 24 hours, administer tocilizumab[c] 8 mg/kg intravenously over 1 hour (not to exceed 800 mg).	Not applicable.
Grade 2 Symptoms require and respond to moderate intervention. Oxygen requirement less than 40% FiO_2 or hypotension responsive to fluids or low dose of one vasopressor or Grade 2 organ toxicity.[b]	Administer tocilizumab 8 mg/kg intravenously over 1 hour (not to exceed 800 mg). Repeat tocilizumab every 8 hours as needed if not responsive to intravenous fluids or increasing supplemental oxygen. Limit to a maximum of 3 doses in a 24-hour period; maximum total of 4 doses if no clinical improvement in the signs and symptoms of CRS. If improving, discontinue tocilizumab.	Manage per Grade 3 if no improvement within 24 hours after starting tocilizumab. If improving, taper corticosteroids.
Grade 3 Symptoms require and respond to aggressive intervention. Oxygen requirement greater than or equal to 40% FiO_2 or hypotension requiring high-dose or multiple vasopressors or Grade 3 organ toxicity or Grade 4 transaminitis.	Per Grade 2 If improving, discontinue tocilizumab.	Administer methylprednisolone 1 mg/kg intravenously twice daily or equivalent dexamethasone (e.g., 10 mg intravenously every 6 hours) until Grade 1, then taper corticosteroids. If improving, manage as Grade 2. If not improving, manage as Grade 4.
Grade 4 Life-threatening symptoms. Requirements for ventilator support or continuous veno-venous hemodialysis (CVVHD), or	Per Grade 2 If improving, discontinue tocilizumab.	Administer methylprednisolone 1000 mg intravenously per day for 3 days. If improving, taper corticosteroids, and manage as Grade 3.

Grade 4 organ toxicity (excluding transaminitis).		If not improving, consider alternate immunosuppressants.

a. Lee et al. 2014.
b. Refer to Table 2 for management of neurologic toxicity.
c. Refer to tocilizumab Prescribing Information for details.

Neurologic Toxicity

Monitor patients for signs and symptoms of neurologic toxicities (Table 2). Rule out other causes of neurologic symptoms. Patients who experience Grade 2 or higher neurologic toxicities should be monitored with continuous cardiac telemetry and pulse oximetry. Provide intensive care supportive therapy for severe or life-threatening neurologic toxicities. Consider non-sedating anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis for any Grade 2 or higher neurologic toxicities.

Table 2. Neurologic Toxicity Grading and Management Guidance

<table>
<tr><th>Neurologic Event[a]</th><th>Concurrent CRS</th><th>No Concurrent CRS</th></tr>
<tr><td>Grade 1
Examples include:
Somnolence – mild drowsiness or sleepiness
Confusion – mild disorientation
Encephalopathy – mild limiting of ADLs
Dysphasia– not impairing ability to communicate</td><td>Administer tocilizumab per Table 1 for management of Grade 1 CRS.</td><td>Supportive care.</td></tr>
<tr><td rowspan="2">Grade 2
Examples include:
Somnolence – moderate limiting instrumental ADLs
Confusion – moderate disorientation
Encephalopathy - limiting instrumental ADLs
Dysphasia moderate impairing ability to communicate spontaneously
Seizure(s)</td><td>Administer tocilizumab per Table 1 for management of Grade 2 CRS.
If not improving within 24 hours after starting tocilizumab, administer dexamethasone 10 mg intravenously every 6 hours until the event is Grade 1 or less, then taper corticosteroids.
If improving, discontinue tocilizumab.
If still not improving, manage as Grade 3.</td><td>Administer dexamethasone 10 mg intravenously every 6 hours until the event is Grade 1 or less.
If improving, taper corticosteroids.</td></tr>
<tr><td colspan="2">Consider non-sedating, anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis.</td></tr>
</table>

<table>
<tr><th>Neurologic Event[a]</th><th>Concurrent CRS</th><th>No Concurrent CRS</th></tr>
<tr><td rowspan="2">Grade 3
Examples include:
Somnolence – obtundation or stupor
Confusion – severe disorientation
Encephalopathy - limiting self-care ADLs
Dysphasia – severe receptive or expressive characteristics, impairing ability to read, write, or communicate intelligibly</td><td>Administer tocilizumab per Table 1 for management of Grade 2 CRS.
In addition, administer dexamethasone 10 mg intravenously with the first dose of tocilizumab and repeat dose every 6 hours. Continue dexamethasone use until the event is Grade 1 or less, then taper corticosteroids.
If improving, discontinue tocilizumab and manage as Grade 2.
If still not improving, manage as Grade 4.</td><td>Administer dexamethasone 10 mg intravenously every 6 hours.
Continue dexamethasone use until the event is Grade 1 or less, then taper corticosteroids
If not improving, manage as Grade 4.</td></tr>
<tr><td colspan="2">Consider non-sedating anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis.</td></tr>
<tr><td rowspan="2">Grade 4
Life-threatening consequences
Urgent intervention indicated
Requirement for mechanical ventilation
Consider cerebral edema</td><td>Administer tocilizumab per Table 1 for management of Grade 2 CRS.
Administer methylprednisolone 1000 mg intravenously per day with first dose of tocilizumab and continue methylprednisolone 1000 mg intravenously per day for 2 more days.
If improving, then manage as Grade 3.
If not improving, consider alternate immunosuppressants.</td><td>Administer methylprednisolone 1000 mg intravenously per day for 3 days.
If improving, then manage as Grade 3.
If not improving, consider alternate immunosuppressants.</td></tr>
<tr><td colspan="2">Consider non-sedating anti-seizure medicines (e.g., levetiracetam) for seizure prophylaxis.</td></tr>
</table>

Abbreviation: ADLs, activities of daily living.

a. Severity based on Common Terminology Criteria for Adverse Events.

3 DOSAGE FORMS AND STRENGTHS

TECARTUS is available as a cell suspension for infusion.

A single dose of TECARTUS contains 2×10^6 CAR-positive viable T cells per kg of body weight (maximum of 2×10^8 CAR-positive viable T cells (for patients 100 kg and above) in approximately 68 mL suspension in an infusion bag *[see How Supplied/Storage and Handling (16)]*.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Cytokine Release Syndrome

CRS, including life-threatening reactions, occurred following treatment with TECARTUS. In ZUMA-2, CRS occurred in 91% (75/82) of patients receiving TECARTUS, including ≥ Grade 3 (Lee grading system[1]) CRS in 18% of patients. Among the patients who died after receiving TECARTUS, one had a fatal CRS event. The median time to onset of CRS was three days (range: 1 to 13 days) and the median duration of CRS was ten days (range: 1 to 50 days). Among patients with CRS, key manifestations (>10%) included fever (99%), hypotension (60%), hypoxia (37%), chills (33%), tachycardia (37%), headache (24%), fatigue (19%), nausea (13%), alanine aminotransferase increased (13%), aspartate aminotransferase increased (12%), and diarrhea (11%). Serious events associated with CRS included hypotension, fever, hypoxia, acute kidney injury, and tachycardia *[see Adverse Reactions (6)]*.

Ensure that a minimum of two doses of tocilizumab are available for each patient prior to infusion of TECARTUS. Monitor patients daily for at least seven days at the certified healthcare facility following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for four weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time *[see Patient Counseling Information (17)]*. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated *[see Dosage and Administration (2.3)]*.

5.2 Neurologic Toxicities

Neurologic events, including those that were life-threatening, occurred following treatment with TECARTUS. In ZUMA-2, neurologic events occurred in 81% of patients, 37% of whom experienced Grade 3 or higher (severe or life-threatening) adverse reactions. The median time to onset for neurologic events was six days (range: 1 to 32 days). Neurologic events resolved for 52 out of 66 (79%) patients with a median duration of 21 days (range: 2 to 454 days). Three patients had ongoing neurologic events at the time of death, including one patient with serious encephalopathy. The remaining unresolved neurologic events were either Grade 1 or Grade 2. Fifty-four (66%) patients experienced CRS before the onset of neurological events. Five (6%) patients did not experience CRS with neurologic events and eight patients (10%) developed neurological events after the resolution of CRS. Eighty-five percent of all treated patients experienced the first CRS or neurological event within the first seven days after TECARTUS infusion.

The most common neurologic events (>10%) included encephalopathy (51%), headache (35%), tremor (38%), aphasia (23%), and delirium (16%). Serious events including encephalopathy, aphasia, and seizures occurred after treatment with TECARTUS.

Monitor patients daily for at least seven days at the certified healthcare facility following infusion for signs and symptoms of neurologic toxicities. Monitor patients for signs or symptoms of neurologic toxicities for four weeks after infusion and treat promptly. *[see Dosage and Administration (2.3)]*.

5.3 YESCARTA and TECARTUS REMS Program

Because of the risk of CRS and neurologic toxicities, TECARTUS is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS Program *[see Boxed Warning and Warnings and Precautions (5.1 and 5.2)]*. The required components of the YESCARTA and TECARTUS REMS Program are:

- Healthcare facilities that dispense and administer TECARTUS must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within two hours after TECARTUS infusion, if needed for treatment of CRS.
- Certified healthcare facilities must ensure that healthcare providers who prescribe, dispense, or administer TECARTUS are trained in the management of CRS and neurologic toxicities.

Further information is available at www.YescartaTecartusREMS.com or 1-844-454-KITE (5483).

5.4 Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, may occur due to dimethyl sulfoxide (DMSO) or residual gentamicin in TECARTUS.

5.5 Severe Infections

Severe or life-threatening infections occurred in patients after TECARTUS infusion. In ZUMA-2, infections (all grades) occurred in 56% of patients. Grade 3 or higher infections, including bacterial, viral, and fungal infections, occurred in 30% of patients. TECARTUS should not be administered to patients with clinically significant active systemic infections. Monitor patients for signs and symptoms of infection before and after TECARTUS infusion and treat appropriately. Administer prophylactic antimicrobials according to local guidelines.

Febrile neutropenia was observed in 6% of patients after TECARTUS infusion and may be concurrent with CRS. In the event of febrile neutropenia, evaluate for infection and manage with broad spectrum antibiotics, fluids, and other supportive care as medically indicated.

Viral Reactivation
Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, can occur in patients treated with drugs directed against B cells. Perform screening for HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines before collection of cells for manufacturing.

5.6 Prolonged Cytopenias

Patients may exhibit cytopenias for several weeks following lymphodepleting chemotherapy and TECARTUS infusion. In ZUMA-2, Grade 3 or higher cytopenias not resolved by Day 30 following TECARTUS infusion occurred in 55% of patients and included thrombocytopenia (38%), neutropenia (37%), and anemia (17%). Monitor blood counts after TECARTUS infusion.

5.7 Hypogammaglobulinemia

B cell aplasia and hypogammaglobulinemia can occur in patients receiving treatment with TECARTUS. In ZUMA-2, hypogammaglobulinemia occurred in 16% of patients. Monitor immunoglobulin levels after treatment with TECARTUS and manage using infection precautions, antibiotic prophylaxis, and immunoglobulin replacement.

The safety of immunization with live viral vaccines during or following TECARTUS treatment has not been studied. Vaccination with live virus vaccines is not recommended for at least six weeks prior to the start of lymphodepleting chemotherapy, during TECARTUS treatment, and until immune recovery following treatment with TECARTUS.

5.8 Secondary Malignancies

Patients treated with TECARTUS may develop secondary malignancies. Monitor life-long for secondary malignancies. In the event that a secondary malignancy occurs, contact Kite at 1-844-454-KITE (5483) to obtain instructions on patient samples to collect for testing.

5.9 Effects on Ability to Drive and Use Machines

Due to the potential for neurologic events, including altered mental status or seizures, patients receiving TECARTUS are at risk for altered or decreased consciousness or coordination in the eight weeks following TECARTUS infusion. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, during this initial period.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Cytokine Release Syndrome *[see Warnings and Precautions (5.1)]*
- Neurologic Toxicities *[see Warnings and Precautions (5.2)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.4)]*
- Severe Infections *[see Warnings and Precautions (5.5)]*
- Prolonged Cytopenias *[see Warnings and Precautions (5.6)]*
- Hypogammaglobulinemia *[see Warnings and Precautions (5.7)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Patients with Relapsed/Refractory Mantle Cell Lymphoma (MCL)

The safety of TECARTUS was evaluated in a Phase 2 single-arm clinical study (ZUMA-2) in which a total of 82 patients with relapsed/refractory MCL received a single dose of CAR-positive viable T cells (2×10^6 or 0.5×10^6 anti-CD19 CAR T cells/kg) that was weight-based *[see Clinical Studies (14.1)]*.

The most common adverse reactions (incidence ≥ 20%) were pyrexia, CRS, hypotension, encephalopathy, fatigue, tachycardia, arrhythmia, infection – pathogen unspecified, chills, hypoxia, cough, tremor, musculoskeletal pain, headache, nausea, edema, motor dysfunction, constipation, diarrhea, decreased appetite, dyspnea, rash, insomnia, pleural effusion, and aphasia. Serious adverse reactions occurred in 66% of patients. The most common serious adverse reactions (> 2%) were encephalopathy, pyrexia, infection – pathogen unspecified, CRS, hypoxia, aphasia, renal insufficiency, pleural effusion, respiratory failure, bacterial infections, dyspnea, fatigue, arrhythmia, tachycardia, and viral infections.

The most common (≥ 10%) Grade 3 or higher reactions were anemia, neutropenia, thrombocytopenia, hypotension, hypophosphatemia, encephalopathy, leukopenia, hypoxia,pyrexia, hyponatremia, hypertension, infection-pathogen unspecified, pneumonia, hypocalcemia, and lymphopenia.

Table 3 summarizes the adverse reactions that occurred in at least 10% of patients treated with TECARTUS and Table 4 describes the laboratory abnormalities of Grade 3 or 4 that occurred in at least 10% of patients.

Table 3. Summary of Adverse Reactions Observed in at Least 10% of Patients Treated with TECARTUS in ZUMA-2 (N=82)

Adverse Reaction	Any Grade (%)	Grade 3 or Higher (%)
Blood and Lymphatic System Disorders		
Coagulopathy [a]	10	2
Cardiac Disorders		
Tachycardias [b]	45	0
Bradycardias [c]	10	0
Non-ventricular Arrhythmias [d]	10	4
Gastrointestinal Disorders		
Nausea	35	1
Constipation	29	0
Diarrhea	28	5
Abdominal pain [e]	17	0
Oral pain [f]	16	0
Vomiting [g]	13	0
Dysphagia	10	2
General Disorders and Administration Site Conditions		
Pyrexia	94	15
Fatigue [h]	48	1
Chills	41	0
Edema [i]	35	2
Pain [j]	17	2
Immune System Disorders		
Cytokine release syndrome	91	18
Hypogammaglobulinemia [k]	16	1
Infections and Infestations		
Infection – pathogen unspecified	43	24
Viral infections	18	4
Bacterial infections	13	6
Metabolism and nutrition disorders		
Decreased appetite	26	0
Musculoskeletal and Connective Tissue Disorders		
Musculoskeletal pain [l]	37	2
Motor dysfunction [m]	17	4
Nervous System Disorders		
Encephalopathy [n]	51	24
Tremor	38	2
Headache [o]	35	1
Aphasia [p]	20	7
Dizziness [q]	18	6

Adverse Reaction	Any Grade (%)	Grade 3 or Higher (%)
Neuropathy [r]	13	2
Psychiatric Disorders		
Insomnia	21	0
Delirium [s]	18	5
Anxiety	16	0
Renal and Urinary Disorders		
Renal insufficiency [t]	18	9
Urine output decreased [u]	11	1
Respiratory, Thoracic and Mediastinal Disorders		
Hypoxia	40	20
Cough [v]	38	0
Dyspnea [w]	24	6
Pleural effusion	21	5
Skin and Subcutaneous Tissue Disorders		
Rash [x]	22	4
Vascular Disorders		
Hypotension [y]	57	27
Hypertension	18	11
Thrombosis [z]	17	4

a. Coagulopathy includes coagulopathy, disseminated intravascular coagulation, international normalized ratio increased.
b. Tachycardias includes tachycardia, sinus tachycardia.
c. Bradycardias includes bradycardia, sinus bradycardia.
d. Non-ventricular arrhythmias includes atrial fibrillation, atrial flutter, cardiac flutter, palpitations, supraventricular tachycardia.
e. Abdominal pain includes abdominal pain, abdominal pain lower, abdominal pain upper, abdominal tenderness.
f. Oral pain includes oral pain, gingival pain, lip pain, oral mucosal erythema, oropharyngeal pain.
g. Vomiting includes vomiting, retching.
h. Fatigue includes fatigue, lethargy, malaise.
i. Edema includes eyelid edema, face edema, generalized edema, localised edema, edema, edema peripheral, periorbital edema, peripheral swelling, scrotal edema, swelling face.
j. Pain includes pain, allodynia, dysaesthesia, ear pain, facial pain, non-cardiac chest pain.
k. Hypogammaglobulinemia includes hypogammaglobulinemia, blood immunoglobulin G decreased.
l. Musculoskeletal pain includes musculoskeletal pain, arthralgia, back pain, bone pain, dysarthria, flank pain, groin pain, myalgia, neck pain, pain in extremity.
m. Motor dysfunction includes asthenia, intensive care acquired weakness, mobility decreased, muscle twitching, muscular weakness, myopathy.
n. Encephalopathy includes encephalopathy, altered state of consciousness, amnesia, balance disorder, cognitive disorder, confusional state, disturbance in attention, dysgraphia, dyskinesia, memory impairment, mental status changes, neurotoxicity, somnolence.
o. Headache includes headache, migraine.
p. Aphasia includes aphasia, communication disorder.
q. Dizziness includes dizziness, presyncope, syncope.
r. Neuropathy includes hyperaesthesia, neuropathy peripheral, paraesthesia, paraesthesia oral.
s. Delirium includes delirium, agitation, disorientation, hallucination, hypomania, irritability, nervousness, personality change.
t. Renal insufficiency includes acute kidney injury, blood creatinine increased.
u. Urine output decreased includes urine output decreased, urinary retention.
v. Cough includes cough, upper-airway cough syndrome.
w. Dyspnea includes dyspnea, dyspnea exertional.
x. Rash includes rash, erythema, rash erythematous, rash maculo-papular, rash pustular.
y. Hypotension includes hypotension, orthostatic hypotension.
z. Thrombosis includes thrombosis, deep vein thrombosis, embolism, pulmonary embolism.

Other clinically important adverse reactions that occurred in less than 10% of patients treated with TECARTUS include the following:

- *Gastrointestinal disorders:* dry mouth (7%)
- *Infections and infestations disorders:* fungal infections (9%)
- *Metabolism and nutrition disorders:* dehydration (6%)
- *Nervous system disorders:* ataxia (7%), seizure (5%), increased intracranial pressure (2%)
- *Respiratory, thoracic and mediastinal disorders:* respiratory failure (6%), pulmonary edema (4%)
- *Skin and subcutaneous tissue disorders:* rash (9%)
- *Vascular disorders:* hemorrhage (7%)

Table 4. Grade 3 or 4 Laboratory Abnormalities Occurring in ≥ 10% of Patients in ZUMA-2 Following TECARTUS Infusion (N = 82)

	Grades 3 or 4 (%)
Leukopenia	95
Neutropenia	95
Lymphopenia	86
Thrombocytopenia	63
Anemia	55
Hypophosphatemia	30
Hypocalcemia	21
Blood uric acid increased	17
Hyponatremia	16
Aspartate Aminotransferase increased	15
Alanine Aminotransferase increased	15
Hypokalemia	10

6.2 Immunogenicity

TECARTUS has the potential to induce anti-product antibodies, which has been evaluated using an enzyme-linked immunosorbent assay (ELISA) for the detection of binding antibodies against FMC63, the originating antibody of the anti-CD19 CAR. To date, no anti-CAR T-cell antibody immunogenicity has been observed. Based on an initial screening assay, 17 patients tested positive for antibodies; however, a confirmatory orthogonal cell-based assay demonstrated that all 17 patients were antibody negative at all time points tested. There is no evidence that the kinetics of initial expansion and persistence of TECARTUS, or the safety or effectiveness of TECARTUS, was altered in these patients.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data with TECARTUS use in pregnant women. No animal reproductive and developmental toxicity studies have been conducted with TECARTUS to assess whether TECARTUS can cause fetal harm when administered to a pregnant woman. It is not known if TECARTUS has the potential to be transferred to the fetus. Based on the mechanism of action of TECARTUS, if the transduced cells cross the placenta, they may cause fetal toxicity, including B cell lymphocytopenia. Therefore, TECARTUS is not recommended for women who are pregnant. Pregnancy after TECARTUS infusion should be discussed with the treating physician.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% - 4% and 15% - 20%, respectively.

8.2 Lactation

Risk Summary

There is no information regarding the presence of TECARTUS in human milk, the effect on the breastfed infant, and the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TECARTUS and any potential adverse effects on the breastfed infant from TECARTUS or from the underlying maternal condition.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Pregnancy status of females with reproductive potential should be verified. Sexually active females of reproductive potential should have a negative pregnancy test prior to starting treatment with TECARTUS.

Contraception

See the prescribing information for fludarabine and cyclophosphamide for information on the need for effective contraception in patients who receive the lymphodepleting chemotherapy.

There are insufficient exposure data to provide a recommendation concerning duration of contraception following treatment with TECARTUS.

Infertility

There are no data on the effect of TECARTUS on fertility.

8.4 Pediatric Use

The safety and efficacy of TECARTUS have not been established in pediatric patients.

8.5 Geriatric Use

Of the 82 patients treated with TECARTUS, 42 were ≥ 65 years of age and 40 were < 65 years of age. No overall differences in safety or effectiveness were observed between patients ≥ 65 years of age and younger patients.

11 DESCRIPTION

TECARTUS is a CD19-directed genetically modified autologous T cell immunotherapy. To prepare TECARTUS, a patient's own T cells are harvested and genetically modified *ex vivo* by retroviral transduction to express a chimeric antigen receptor (CAR) comprising a murine anti-CD19 single-chain variable fragment (scFv) linked to CD28 and CD3-zeta co-stimulatory domains. The anti-CD19 CAR T cells are expanded and infused back into the patient, where they can recognize and eliminate CD19-expressing target cells.

TECARTUS is prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. The mononuclear cells are enriched for T cells and activated with anti-CD3 and anti-CD28 antibodies in the presence of IL-2, then transduced with a replication-incompetent retroviral vector containing the anti-CD19 CAR transgene. The transduced T cells are expanded in cell culture, washed, formulated into a suspension, and cryopreserved. The manufacture of TECARTUS includes a T cell enrichment step that may reduce the likelihood of circulating CD19-expressing tumor cells in patients' leukapheresis material driving the activation, expansion, and exhaustion of the anti-CD19 CAR T cells during the *ex vivo* manufacturing process. The product must pass a sterility test before release for shipping as a frozen suspension in a patient-specific infusion bag. The product is thawed prior to infusion *[see Dosage and Administration (2.2), How Supplied/Storage and Handling (16)]*.

In addition to T cells, TECARTUS may contain natural killer (NK) cells. The formulation contains CryoStor (dimethyl sulfoxide [DMSO], final concentration, 5%), sodium chloride (NaCl), and Human Serum Albumin (HSA).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

TECARTUS, a CD19-directed genetically modified autologous T cell immunotherapy, binds to CD19-expressing cancer cells and normal B cells. Studies demonstrated that following anti-CD19 CAR T cell engagement with CD19-expressing target cells, the CD28 and CD3-zeta co-stimulatory domains 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 killing of CD19-expressing cells.

12.2 Pharmacodynamics

After TECARTUS infusion, pharmacodynamic responses were evaluated over a four-week interval by measuring transient elevation of cytokines, chemokines, and other molecules in blood. Levels of cytokines and chemokines such as IL-6, IL-8, IL-10, IL-15, TNF-α, IFN-γ, and sIL2Rα were analyzed. Peak elevation was generally observed between four and eight days after infusion, and levels generally returned to baseline within 28 days.

Due to the on-target effect of TECARTUS, a period of B cell aplasia is expected.

12.3 Pharmacokinetics

Following infusion (target dose of 2×10^6 anti-CD19 CAR T cells/kg) of TECARTUS, anti-CD19 CAR T cells exhibited an initial rapid expansion followed by a decline to near baseline levels by three months. Peak levels of anti-CD19 CAR T cells occurred within the first seven to 15 days after TECARTUS infusion.

The number of anti-CD19 CAR T cells in blood was associated with objective response [complete remission (CR) or partial remission (PR)]. The median peak anti-CD19 CAR T cell level in responders was 102.4 cells/μL (range: 0.2 to 2589.5 cells/μL; n = 51), and in nonresponders was 12.0 cells/μL (range: 0.2 to 1364.0 cells/μL, n = 8). The median $AUC_{Day\ 0\text{-}28}$ in patients with an objective response was 1487.0 cells/μL•days (range: 3.8 to 2.77E+04 cells/μL•days; n = 51) versus 169.5 cells/μL•days in nonresponders (range: 1.8 to 1.17E+04 cells/μL•days; n = 8).

Median peak anti-CD19 CAR T-cell and $AUC_{0\text{-}28}$ levels in patients who received neither corticosteroids nor tocilizumab (peak: 24.7 cells/μL; $AUC_{0\text{-}28}$: 360.4 cells/μL•days, n = 18) was similar to patients who received corticosteroids alone (peak: 24.2 cells/μL; $AUC_{0\text{-}28}$: 367.8 cells/μL•days, n = 2); both groups were lower than patients who received tocilizumab alone (peak: 86.5 cells/μL; $AUC_{0\text{-}28}$: 1188.9 cells/μL•days, n = 10); the highest exposure was in patients who received both corticosteroids and tocilizumab (peak: 167.2 cells/μL; $AUC_{0\text{-}28}$: 1996.0 cells/μL•days, n = 37).

Median peak anti-CD19 CAR T-cell values were 74.1 cells/μL in patients ≥ 65 years of age (n = 39) and 112.5 cells/μL in patients < 65 years of age (n = 28). Median anti-CD19 CAR T-cell $AUC_{Day\ 0-28}$ values were 876.5 cells/μL•day in patients ≥ 65 years of age and 1640.2 cells/μL•day in patients < 65 years of age.

Gender had no significant impact on $AUC_{Day\ 0-28}$ and C_{max} of TECARTUS.

Hepatic and renal impairment studies of TECARTUS were not conducted.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity or genotoxicity studies have been conducted with TECARTUS. No studies have been conducted to evaluate the effects of TECARTUS on fertility.

14 CLINICAL STUDIES

14.1 Relapsed or Refractory Mantle Cell Lymphoma

A single-arm, open-label, multicenter trial (ZUMA-2; NCT02601313) evaluated the efficacy and safety of a single infusion of TECARTUS in adult patients with relapsed or refractory mantle cell lymphoma (MCL) who had previously received anthracycline- or bendamustine-containing chemotherapy, an anti-CD20 antibody, and a Bruton tyrosine kinase inhibitor (BTKi; ibrutinib or acalabrutinib). Eligible patients also had disease progression after their last regimen or refractory disease to their most recent therapy. The study excluded patients with active or serious infections, prior allogeneic hematopoietic stem cell transplant (HSCT), detectable cerebrospinal fluid malignant cells or brain metastases, and any history of central nervous system (CNS) lymphoma or CNS disorders.

Seventy-four patients were leukapheresed, five (7%) of whom did not begin conditioning chemotherapy or receive TECARTUS: three (4%) experienced manufacturing failure, one (1%) died of progressive disease, and one (1%) withdrew from the study. One patient (1%) received lymphodepleting chemotherapy but did not receive TECARTUS due to ongoing active atrial fibrillation. Sixty-eight of the patients who were leukapheresed received a single infusion of TECARTUS, and 60 of these patients were followed for at least six months after their first objective disease response, qualifying them as efficacy-evaluable. Among the 60 efficacy-evaluable patients, 2×10^6 CAR-positive viable T cells/kg were administered to 54 (90%). The remaining six (10%) patients received doses of 1.0, 1.6, 1.8, 1.8, 1.9, and 1.9×10^6 CAR-positive viable T cells/kg.

Of the 60 efficacy-evaluable patients, the median age was 65 years (range: 38 to 79 years), 51 (85%) were male, and 56 (93%) were white. Most (50 patients; 83%) had stage IV disease. Twenty patients (33% of 60) had baseline bone marrow examinations performed per protocol; of these, ten (50%) were negative, eight (40%) were positive, and two (10%) were indeterminate. The median number of prior therapies among all 60 efficacy-evaluable patients was three (range: two to five). Twenty-six (43%) of the patients had relapsed after or were refractory to autologous HSCT. Twenty-one (35%) had relapsed after their last therapy for MCL, while 36 (60%) were refractory to their last therapy for MCL. Among the 60 efficacy-evaluable patients, 14 (23%) had blastoid MCL. Following leukapheuresis and prior to administration of TECARTUS, 21 (35%) of the 60 patients received bridging therapy. Sixteen (27%) were treated with a BTKi, 9 (15%) with a corticosteroid, and 4 (7%) with both a BTKi and a corticosteroid.

Among the 60 efficacy-evaluable patients, the median time from leukapheresis to product delivery was 15 days (range: 11 to 28 days), and the median time from leukapheresis to product infusion was 27 days (range: 19 to 63 days). The protocol-defined lymphodepleting chemotherapy regimen of cyclophosphamide 500 mg/m^2 intravenously and fludarabine 30 mg/m^2 intravenously, both given on each of the fifth, fourth, and third days before TECARTUS infusion, was administered to 53 (88%) of the 60 efficacy-evaluable patients. The remaining seven patients (12%) either received lymphodepletion over four or more days or received

TECARTUS four or more days after completing lymphodepletion. All treated patients received TECARTUS infusion on Day 0 and were hospitalized until at least Day 7.

The primary endpoint of objective response rate (ORR) per the Lugano Classification (2014) in patients treated with TECARTUS as determined by an independent review committee is provided in Table 5. The median time to response was 28 days (range: 24 to 92 days) with a median follow-up time for DOR of 8.6 months.

Table 5 Efficacy Results in Adult Patients with Relapsed/Refractory MCL

	Efficacy-Evaluable Patients N = 60	**All Leukapheresed Patients (ITT) N = 74**
Response Rate		
Objective Response Rate[a], n (%) [95% CI]	52 (87%) [75, 94]	59 (80%) [69, 88]
Complete Remission Rate, n (%)[95% CI]	37 (62%) [48, 74]	41 (55%) [43, 67]
Partial Remission Rate, n (%) [95% CI]	15 (25%) [15, 38]	18 (24%) [15, 36]
Duration of Response (DOR)		
Median in months [95% CI] Range[b] in months	NR [8.6, NE] 0.0+, 29.2+	NR [8.6, NE] 0.0+, 29.2+
DOR, if best response is CR, median in months [95% CI] Range[b] in months	NR [13.6, NE] 1.9+, 29.2+	NR [13.6, NE] 0.0+, 29.2+
DOR, if best response is PR, median in months [95% CI] Range[b] in months	2.2 [1.5, 5.1] 0.0+, 22.1+	2.2 [1.5, 5.1] 0.0+, 22.1+
Median Follow-up for DOR in months[c]	8.6	8.1

CI, confidence interval; CR, complete remission; DOR, duration of response; NE, not estimable; NR, not reached; PR, partial remission.

a. Among all responders. DOR is measured from the date of first objective response to the date of progression or death.

b. A + sign indicates a censored value.

c. At the time of primary analysis.

15 REFERENCES

1. Lee DW et al (2014). Current concepts in the diagnosis and management of cytokine release syndrome. Blood. 2014 Jul 10; 124(2): 188-195.

16 HOW SUPPLIED/STORAGE AND HANDLING

TECARTUS is supplied in an infusion bag (NDC 71287-219-01) containing approximately 68 mL of frozen suspension of genetically modified autologous T cells in 5% DMSO and human serum albumin.
Each TECARTUS infusion bag is individually packed in a metal cassette (NDC 71287-219-02). TECARTUS is stored in the vapor phase of liquid nitrogen and supplied in a liquid nitrogen dry shipper.

- Match the identity of the patient with the patient identifiers on the cassette and infusion bag upon receipt.
- Store TECARTUS frozen in the vapor phase of liquid nitrogen (less than or equal to minus 150ºC).
- Thaw before using *[see Dosage and Administration (2)].*

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Ensure that patients understand the risk of manufacturing failure (4% in clinical trial). In case of a manufacturing failure, a second manufacturing of TECARTUS may be attempted. In addition, while the patient awaits the product, additional chemotherapy (not the lymphodepletion) may be necessary and may increase the risk of adverse events during the pre-infusion period.

Advise patients to seek immediate attention for any of the following:

- Cytokine Release Syndrome (CRS) - Signs or symptoms associated with CRS, including fever, chills, fatigue, tachycardia, nausea, hypoxia, and hypotension *[see Warnings and Precautions (5.1) and Adverse Reactions (6)]*.
- Neurologic Toxicities - Signs or symptoms associated with neurologic events, including encephalopathy, seizures, changes in level of consciousness, speech disorders, tremors, and confusion *[see Warnings and Precautions (5.2) and Adverse Reactions (6)]*.
- Severe Infections - Signs or symptoms associated with infection *[see Warnings and Precautions (5.5) and Adverse Reactions (6)]*.
- Prolonged Cytopenia - Signs or symptoms associated with bone marrow suppression, including neutropenia, anemia, thrombocytopenia, or febrile neutropenia *[see Warnings and Precautions (5.6) and Adverse Reactions (6)].*

Advise patients of the need to:

- Refrain from driving or operating heavy or potentially dangerous machinery for at least eight weeks after TECARTUS infusion *[see Warnings and Precautions (5.9)]*.
- Have periodic monitoring of blood counts.
- Contact Kite at 1-844-454-KITE (5483) if they are diagnosed with a secondary malignancy *[see Warnings and Precautions (5.8)]*.

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MEDICATION GUIDE

TECARTUS (pronounced tek-ahr-tuhs)
(brexucabtagene autoleucel)

Read this Medication Guide before you start your TECARTUS 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 Medication Guide does not take the place of talking with your healthcare provider about your treatment.

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

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

- Fever (100.4°F/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 TECARTUS and to show them your TECARTUS Patient Wallet Card. Your healthcare provider may give you other medicines to treat your side effects.

What is TECARTUS?

TECARTUS is a treatment for your mantle cell lymphoma. It is used following disease progression while on or after other treatment. TECARTUS 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 TECARTUS, 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 TECARTUS?

- Since TECARTUS 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 TECARTUS.
- Before you get TECARTUS, you will get three days of chemotherapy to prepare your body.
- When your TECARTUS 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 seven days after the infusion.

- You should plan to stay close to the location where you received your treatment for at least four weeks after getting TECARTUS. Your healthcare provider will help you with any side effects that may occur.
- You may be hospitalized for side effects. 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 TECARTUS?

- Do not drive, operate heavy machinery, or do other dangerous things for eight weeks after you get TECARTUS 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 TECARTUS?

The most common side effects of TECARTUS include**:**

- Fever (100.4°F/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

These are not all the possible side effects of TECARTUS. Call your healthcare provider about any side effects that concern you. You may report side effects to the FDA at 1-800-FDA-1088.

General information about the safe and effective use of TECARTUS

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about TECARTUS, talk with your healthcare provider. You can ask your healthcare provider for information about TECARTUS that is written for health professionals. You can get additional information by contacting Kite at 1-844-454-KITE (5483) or at www.Tecartus.com.

What are the ingredients in TECARTUS?

Active ingredients: brexucabtagene autoleucel.

Inactive ingredients: albumin (human); DMSO.