

יולי 2026

**עדכון עלון לרופא ולצרכן לתכשיר:****Yescarta®****Cells dispersion for intravenous infusion****(axicabtagene ciloleucel)**

רופאים ורוקחים נכבדים,

חברת גילימד סינסז ישראל בע"מ מבקשת להודיעכם על עדכון עלונים לתכשיר בנדון.

ההתוויה הרשומה לתכשיר בישראל:

Yescarta is indicated for the treatment of 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.

Yescarta is indicated for the treatment of adult patients with relapsed or refractory (r/r) diffuse large B cell lymphoma (DLBCL) and primary mediastinal large B cell lymphoma (PMBCL), after two or more lines of systemic therapy .

Limitation of Use: Yescarta is not indicated for the treatment of patients with primary or secondary central nervous system lymphoma.

Yescarta is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.

השינויים מסומנים בעלון המצורף כאשר הטקסט המודגש באדום הוסף לעלון ואילו הטקסט המחוקק בצהוב נגרע ממנו. הסימונים בצהוב הינם החמרות במידע הבטיחותי. העדכונים המשמעותיים ביותר מופיעים במכתב זה, קיימים עדכונים מינוריים נוספים.

העלונים לרופא ולצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות

<https://israeldrugs.health.gov.il/#/byDrug/drugs/index.html>

כמו כן, ניתן לקבל מודפסים על ידי פנייה לבעל הרישום:

גילימד סינסז ישראל בע"מ, רחוב החרש 4, ת.ד. 6090, פארק העסקים הוד השרון 4524075, ישראל
התכשיר זמין בכל קופות החולים.

בברכה,

מאיה מלל

רוקחת ממונה, גילימד סינסז ישראל בע"מ

העדכונים המהותיים בעלון לרופא:

4.4 Special warnings and precautions for use

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Neurologic adverse reactions

Severe neurologic adverse reactions, also known as immune effector cell-associated neurotoxicity syndrome (ICANS), have been very commonly observed in patients treated with Yescarta, which could be life-threatening or fatal. The median time to onset was 6 days (range: 1 to 133 days) in ZUMA-1 and ZUMA-7, and 7 days (range: 1 to 177 days) in ZUMA-5 following Yescarta infusion (see section 4.8). Patients with a history of CNS disorders such as seizures or cerebrovascular ischaemia may be at increased risk. Fatal and serious cases of cerebral oedema have been reported in patients treated with Yescarta **with most cases occurring in patients with ICANS. The risk for cerebral oedema may be higher in PMBCL patients (see section 4.8).** Patients must be monitored for signs and symptoms of neurologic adverse reactions. Patients must be monitored at least daily for 10 days at the qualified clinical facility following infusion for signs and symptoms of neurologic toxicity/ICANS. After the first 10 days following the infusion, the patient is to be monitored at the physician's discretion. Patients are to be counselled to remain within proximity of a qualified clinical facility for at least 4 weeks following infusion and to seek immediate medical attention should signs or symptoms of neurologic toxicity/ICANS occur. Vital signs and organ functions must be monitored depending on the severity of the reaction.

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.

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4.8 Undesirable effects

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Table 1: Adverse drug reactions identified with Yescarta

System Organ Class (SOC)	Frequency	Adverse reactions
Infections and infestations		
	Very common	Unspecified pathogen infections Viral infection Bacterial infection
	Common	Fungal infection
Neoplasms benign, malignant and unspecified (including cysts and polyps)		
	Uncommon	Secondary malignancy of T-cell origin
Blood and lymphatic system disorders		
	Very common	Febrile neutropenia [#] Neutropenia [#] Lymphopenia [#] Leukopenia [#] Anaemia [#] Thrombocytopenia [#]
	Common	Coagulopathy ^a
Immune system disorders		

System Organ Class (SOC)	Frequency	Adverse reactions
	Very common	Cytokine Release Syndrome Immunoglobulins decreased ^b
	Common	Hypersensitivity
	Uncommon	Haemophagocytic Lymphohistiocytosis*
Metabolism and nutrition disorders		
	Very common	Hyponatraemia [#] Hypophosphataemia [#] Hyperuricemia ^{***} Hyperglycaemia [#] Decreased appetite ^c
	Common	Hypokalaemia [#] Hypocalcaemia [#] Hypoalbuminaemia [#] Dehydration ^d Weight decreased
Psychiatric disorders		
	Very common	Delirium ^e Insomnia
	Common	Anxiety Affective disorder ^f
Nervous system disorders		
	Very common	Encephalopathy ^g Tremor ^h Headache ⁱ Dizziness ^j
	Common	Ataxia ^k Seizures, including status epilepticus Hemiparesis Facial paralysis ^l Neuropathy peripheral ^m Myoclonus
	Uncommon	Quadriplegia Spinal cord oedema Myelitis Dyscalculia Cerebral oedema ^{##}
Eye disorders		
	Common	Visual impairment ⁿ
Cardiac disorders		
	Very common	Tachycardia ^o Arrhythmia ^p
	Common	Cardiac arrest Cardiac failure ^q
Vascular disorders		
	Very common	Hypotension ^r Hypertension
	Common	Thrombosis ^s Haemorrhage ^t
Respiratory, thoracic and mediastinal disorders		
	Very common	Cough ^u
	Common	Respiratory failure ^v Hypoxia ^w Pleural effusion Pulmonary oedema

System Organ Class (SOC)	Frequency	Adverse reactions
		Dyspnoea ^x Nasal inflammation ^y
Gastrointestinal disorders		
	Very common	Vomiting Diarrhoea ^z Constipation Abdominal pain ^{aa} Nausea
	Common	Dysphagia ^{***} Dry mouth ^{bb}
Hepatobiliary disorders		
	Very common	Transaminases increased ^{cc}
	Common	Hyperbilirubinaemia ^{dd}
Skin and subcutaneous tissue disorders		
	Very common	Rash ^{ee}
Musculoskeletal and connective tissue disorders		
	Very common	Motor dysfunction ^{ff} Musculoskeletal pain ^{gg}
	Uncommon	Rhabdomyolysis
Renal and urinary disorders		
	Common	Renal impairment ^{hh}
General disorders and administration site conditions		
	Very common	Fever ⁱⁱ Oedema ^{jj} Fatigue ^{kk} Chills
	Common	Infusion related reaction Pain
	Uncommon	Multiple organ dysfunction syndrome

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העדכונים המהותיים בעלון לצרכן:

4. תופעות לוואי

תופעות לוואי שאינן שכיחות (עלולות להשפיע על עד 1 מכל 100 אנשים)

- מצבים המעידים על דלקת מערכתית חמורה. תסמינים יכולים לכלול חום, פריחה, הגדלה של הכבד, הטחול ובלוטות הלימפה.
- **נפיחות של המוח (בצקת מוחית).**
- תפקוד לקוי של לפחות 2 איברים (לדוגמא: כבד, ריאות וכליות), מצב אשר מצריך טיפול רפואי ולא פרוצדורה רפואית על מנת להחזיר את התפקוד הרגיל של האיבר.