



CLINICIAN'S GUIDE

The only recombinant urate-oxidase FDA-approved for the initial management of uric acid in patients with leukemia and lymphoma who are receiving anticancer therapy¹

Learn more at ELITEKpro.com

Indication

ELITEK is indicated for the initial management of plasma uric acid levels in patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anticancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid. ELITEK is indicated only for a single course of treatment.

Important Safety Information

WARNING: HYPERSENSITIVITY REACTIONS, HEMOLYSIS, METHEMOGLOBINEMIA, AND INTERFERENCE WITH URIC ACID MEASUREMENTS

- **Hypersensitivity Reactions:** ELITEK can cause serious and fatal hypersensitivity reactions including anaphylaxis. Immediately and permanently discontinue ELITEK in patients who experience a serious hypersensitivity reaction.
- **Hemolysis:** Do not administer ELITEK to patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Immediately and permanently discontinue ELITEK in patients developing hemolysis. Screen patients at higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) prior to starting ELITEK.
- **Methemoglobinemia:** ELITEK can result in methemoglobinemia in some patients. Immediately and permanently discontinue ELITEK in patients developing methemoglobinemia.
- **Interference with Uric Acid Measurements:** ELITEK enzymatically degrades uric acid in blood samples left at room temperature. Collect blood samples in pre-chilled tubes containing heparin and immediately immerse and maintain sample in an ice water bath. Assay plasma samples within 4 hours of collection.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including Boxed WARNING.



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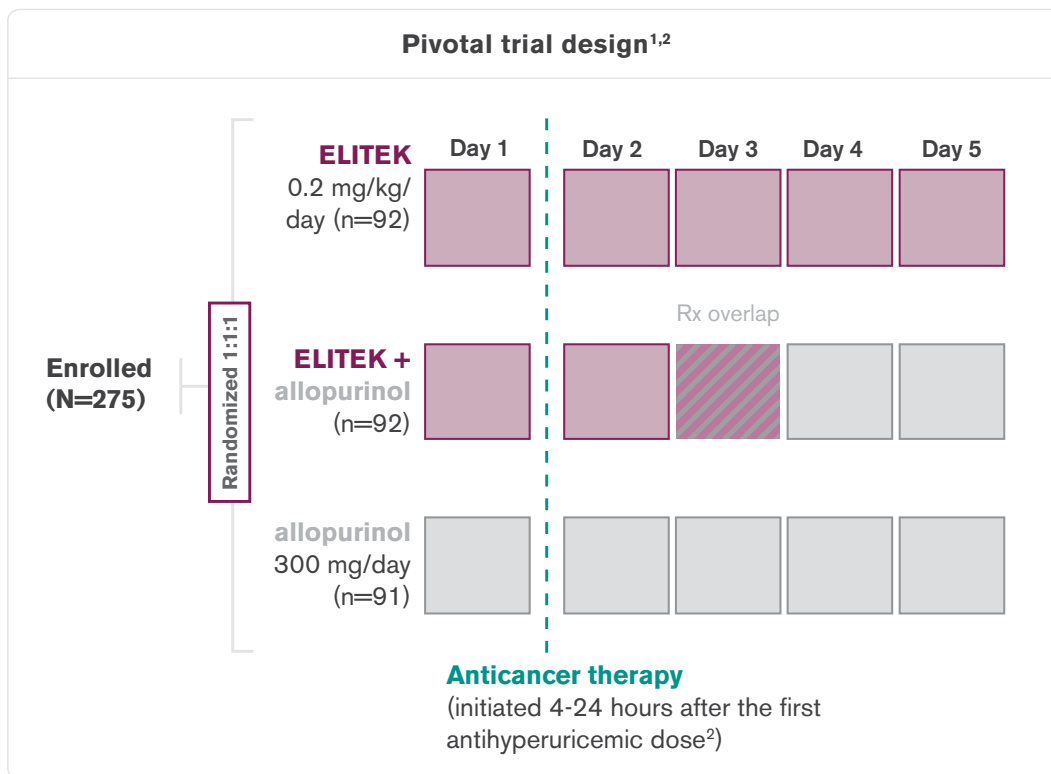
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TLS=tumor lysis syndrome.

TRIAL DESIGN

Prophylactic use of ELITEK was studied in a phase 3 trial where ELITEK was initiated prior to anticancer therapy^{1,2}

- **Phase 3 study:** randomized, multicenter, open-label study in adults with leukemia, lymphoma, and solid tumor malignancies at risk for hyperuricemia and TLS
- **Primary endpoint:** response rate defined as the proportion of patients with plasmic uric acid levels maintained at ≤ 7.5 mg/dL between 3 and 7 days after initiation of antihyperuricemic treatment



Note: ELITEK was also studied in pediatric patients. Ask your representative for details.

Important Safety Information, cont'd

- Among the 347 (265 pediatric; 82 adult) patients for whom all adverse reactions (ARs) regardless of severity were assessed in Studies 1, 2 and 3, as well as an uncontrolled safety trial, the most common ARs ($\geq 10\%$) were vomiting (50%), fever (46%), nausea (27%), headache (26%), abdominal pain (20%), constipation (20%), diarrhea (20%), mucositis (15%), and rash (13%).

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BASELINE TLS RISK

Majority of patients studied were at high risk for TLS associated with hyperuricemia but had normal uric acid levels at baseline²

9 out of 10

patients were at high risk

82%

of patients had normal uric acid levels (≤ 7.5 mg/dL)

Patients meeting at least one of the following criteria were enrolled in the pivotal trial²:

High risk ²⁻⁴	Intermediate (potential) risk ²
Aggressive lymphoma/leukemia (defined by REAL) <ul style="list-style-type: none"> • DLBCL • Anaplastic large cell lymphoma • Peripheral T-cell lymphomas • Burkitt lymphoma • Lymphoblastic lymphoma • CLL 	Aggressive lymphoma/leukemia, not limited to the REAL definition, with LDH $\geq 2x$ the upper limit of normal
AML	Any stage III to IV lymphoma or leukemia
Elevated plasma uric acid levels at baseline (>7.5 mg/dL)	Stage I or II disease with bulky lymph node/tumor (>5 cm) involvement
High-grade MDS with $>10\%$ bone marrow blast involvement	
CML in blast crisis	

AML=acute myeloid leukemia; CLL=chronic lymphocytic leukemia; CML=chronic myeloid leukemia; DLBCL=diffuse large-B-cell lymphoma; LDH=lactate dehydrogenase; MDS=myelodysplastic syndrome; REAL=Revised European American Classification of Lymphoid Neoplasms.

ELITEK is recommended for patients at high and intermediate (potential) risk for development of TLS associated with hyperuricemia⁵

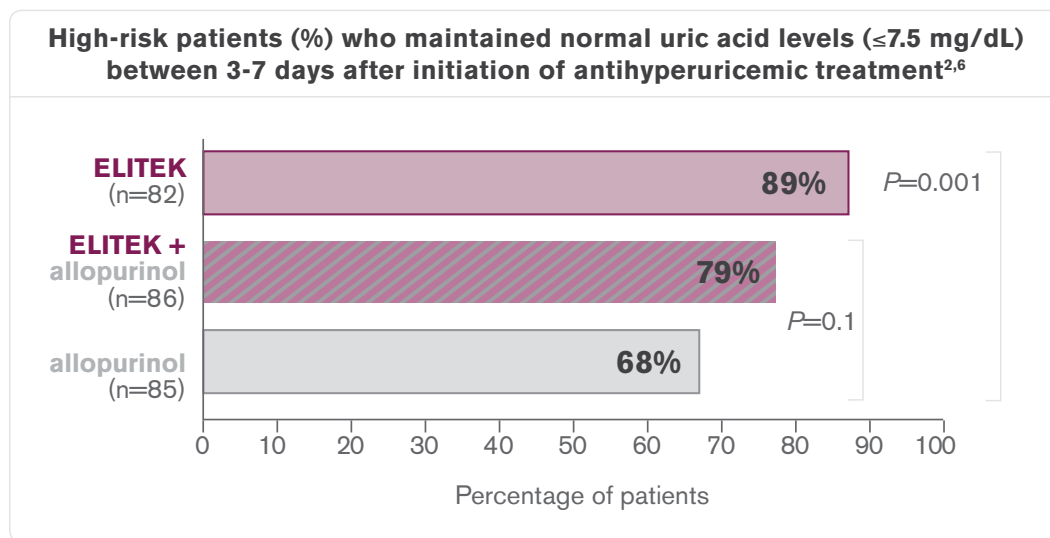
Important Safety Information, cont'd

- Among the 275 adult patients in Study 4, hypersensitivity reactions occurred in 4.3% of patients treated with ELITEK alone and 1.1% of patients treated with the ELITEK plus oral allopurinol. Hypersensitivity reactions included arthralgia, injection site irritation, peripheral edema, and rash. The most common Grade 3-4 ARs regardless of relationship to study drug in Study 4 (ELITEK alone; ELITEK plus oral allopurinol; oral allopurinol alone) were sepsis (5.4%; 6.5%; 4.4%), hypophosphatemia (4.3%; 6.5%; 6.6%), anxiety (3.3%; 0%; 0%), abdominal pain (3.3%; 4.3%; 2.2%), hyperbilirubinemia (3.3%; 2.2%; 4.4%), and increased alanine aminotransferase (3.3%; 4.3%; 2.2%), respectively.

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RESULTS IN HIGH-RISK PATIENTS

ELITEK given prophylactically maintained normal uric acid levels ≤ 7.5 mg/dL in significantly more high-risk patients vs allopurinol²



- Results were consistent with the overall patient population (**primary endpoint**): 87% (n=92) of patients receiving ELITEK prophylactically maintained uric acid levels ≤ 7.5 mg/dL vs 66% (n=91) of patients receiving allopurinol ($P=0.001$)²
- ELITEK + allopurinol maintained normal uric acid in 78% (n=92) of patients ($P=NS$ vs allopurinol)²

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for CLL/SLL: Consider prophylaxis with rasburicase in patients receiving venetoclax with high tumor burden and elevated baseline uric acid⁷

SLL=small lymphocytic lymphoma.

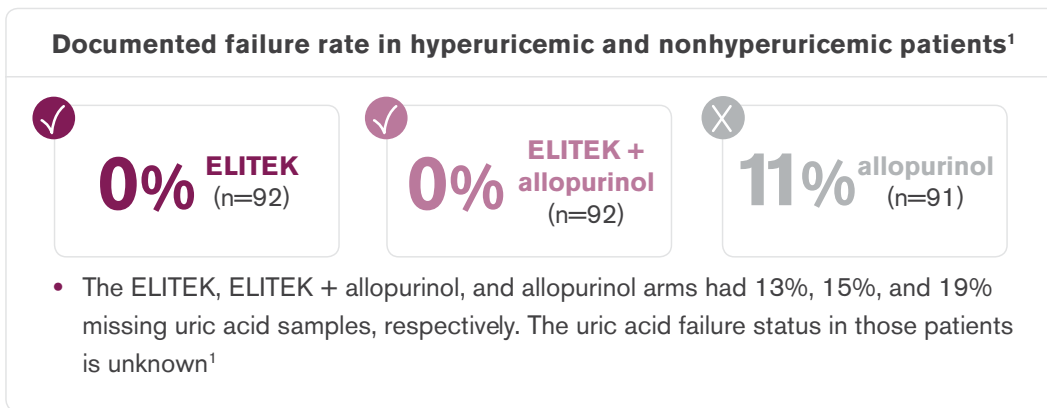
Important Safety Information, cont'd

- The following serious ARs occurred with a difference in incidence of $\geq 2\%$ in patients receiving ELITEK vs. oral allopurinol in Study 1 and Study 4: pulmonary hemorrhage, respiratory failure, supraventricular arrhythmias, ischemic coronary artery disorders, and abdominal and gastrointestinal infections.

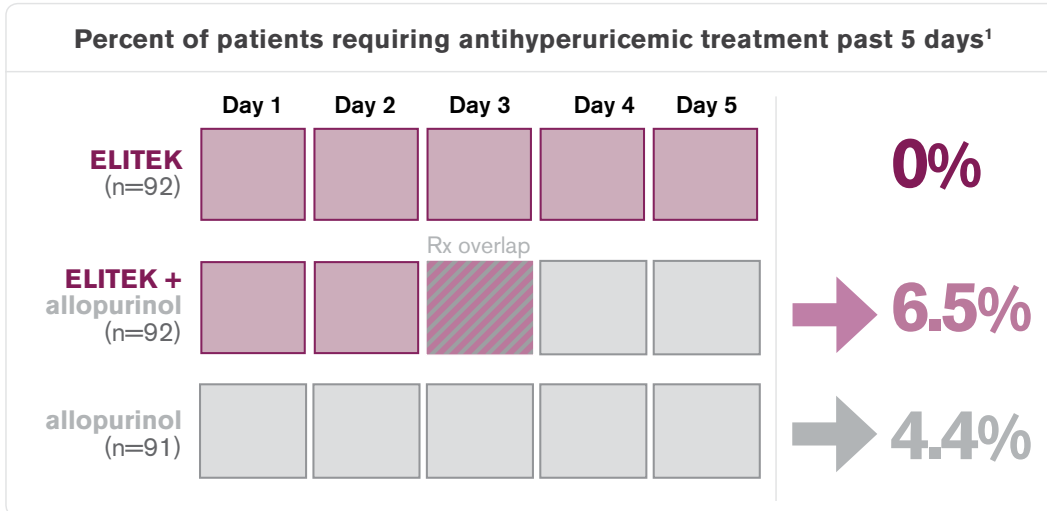
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DOCUMENTED FAILURE RATE

Unlike allopurinol, ELITEK maintained normal uric acid levels in 100% of assessable patients¹



Unlike allopurinol, no patients receiving ELITEK required antihyperuricemic treatment beyond 5 days¹



Important Safety Information, cont'd

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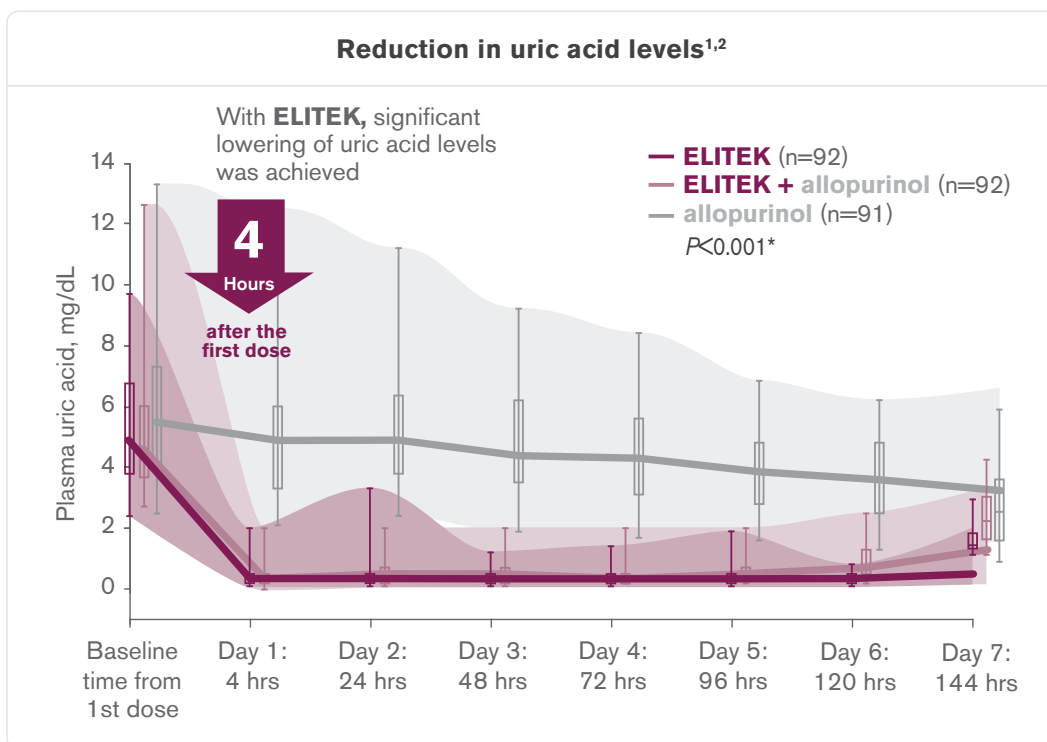
URIC ACID REDUCTION IN PATIENTS WITH BASELINE HYPERURICEMIA



ELITEK given prophylactically significantly and rapidly lowered uric acid levels^{1,2}

18% of patients were hyperuricemic (>7.5 mg/dL) at baseline and therefore were considered at high risk of developing TLS²

- 96% of ELITEK patients achieved uric acid levels ≤ 2 mg/dL within 4 hours after their first dose vs 0% with allopurinol^{1,2}



*Plasma uric acid AUC from day 1 through day 7 was significantly lower for ELITEK and ELITEK + allopurinol than for allopurinol alone ($P < 0.001$).

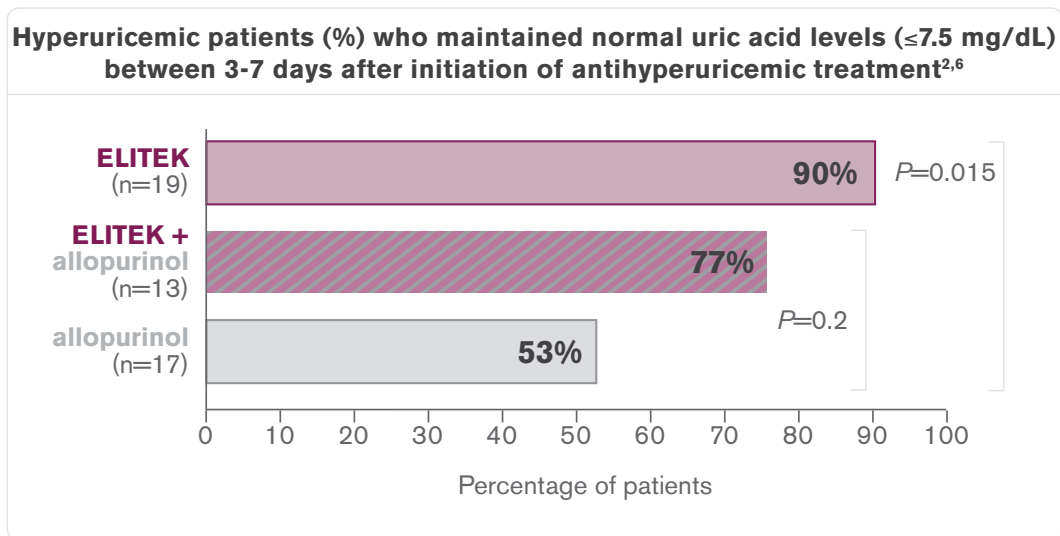
Important Safety Information, cont'd

- Hemolysis:** Do not administer **ELITEK** to patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Immediately and permanently discontinue **ELITEK** in patients developing hemolysis. Screen patients at higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) prior to starting **ELITEK**.

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RESULTS IN HYPERURICEMIC PATIENTS

ELITEK given prophylactically maintained normal uric acid levels ≤ 7.5 mg/dL in significantly more patients with hyperuricemia at baseline vs allopurinol²



- Results were consistent with the overall patient population (**primary endpoint**): 87% (n=92) of patients receiving ELITEK prophylactically maintained uric acid levels ≤ 7.5 mg/dL vs 66% (n=91) of patients receiving allopurinol ($P=0.001$)²
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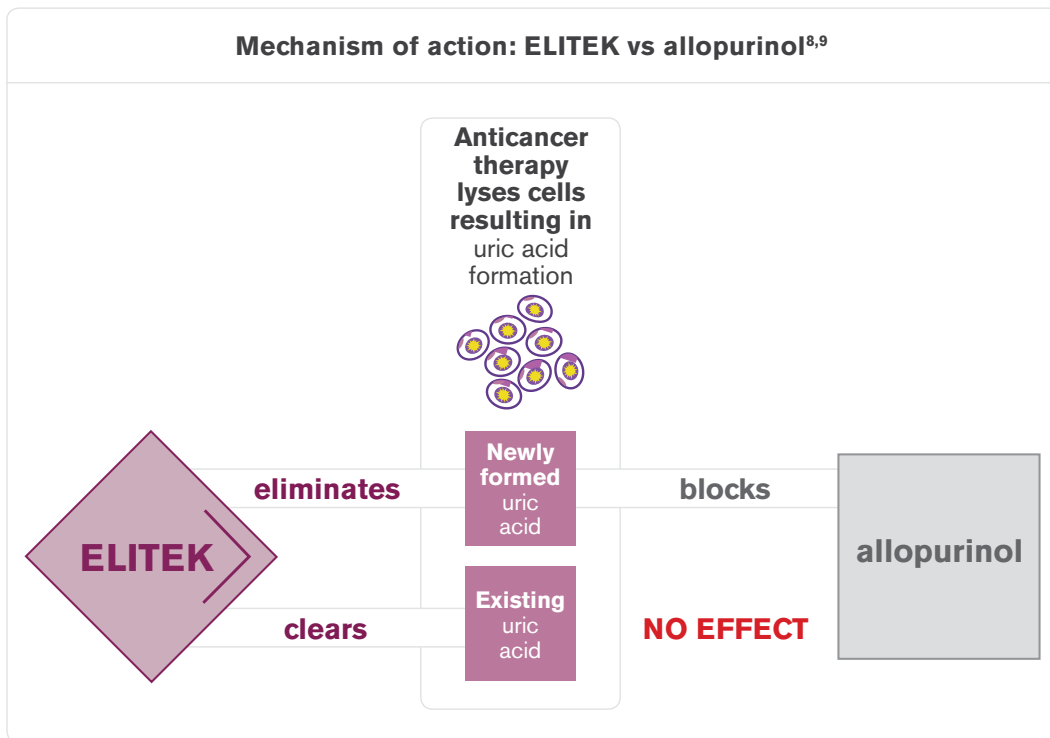
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- **Interference with Uric Acid Measurements:** ELITEK enzymatically degrades uric acid in blood samples left at room temperature. Collect blood samples in pre-chilled tubes containing heparin and immediately immerse and maintain sample in an ice water bath. Assay plasma samples within 4 hours of collection.

MECHANISM OF ACTION

Unlike allopurinol, ELITEK clears new and existing uric acid⁸

- Allopurinol blocks the formation of new uric acid but has no effect on existing uric acid



Important Safety Information, cont'd

- Among the 347 (265 pediatric; 82 adult) patients for whom all adverse reactions (ARs) regardless of severity were assessed in Studies 1, 2 and 3, as well as an uncontrolled safety trial, the most common ARs ($\geq 10\%$) were vomiting (50%), fever (46%), nausea (27%), headache (26%), abdominal pain (20%), constipation (20%), diarrhea (20%), mucositis (15%), and rash (13%).

ADVERSE REACTIONS



ELITEK has a proven safety profile¹

Per-patient incidence of selected adverse reactions ¹						
Adverse Reaction*	ELITEK % (n=92)		ELITEK + allopurinol % (n=92)		allopurinol % (n=91)	
	All Grades	Grades 3/4	All Grades	Grades 3/4	All Grades	Grades 3/4
Nausea	57.6	1.1	60.9	1.1	54.9	2.2
Peripheral edema	50	2.2	43.5	3.3	42.9	6.6
Vomiting	38	1.1	37	0	30.8	1.1
Anxiety	23.9	3.3	17.4	0	17.6	0
Abdominal pain	21.7	3.3	33.7	4.3	25.3	2.2
Hypophosphatemia	17.4	4.3	22.8	6.5	16.5	6.6
Hyperbilirubinemia	16.3	3.3	14.1	2.2	7.7	4.4
Pharyngolaryngeal pain	14.1	1.1	20.7	0	9.9	0
Sepsis	12	5.4	7.6	6.5	4.4	4.4
Fluid overload	12	0	6.5	0	3.3	1.1
Increased ALT	10.9	3.3	27.2	4.3	17.6	2.2
Hyperphosphatemia	9.8	0	15.2	0	8.8	1.1




Overall incidence $\geq 10\%$ in any ELITEK arm and the difference between any ELITEK arm vs allopurinol $\geq 5\%$.¹

*Events were reported and graded according to the NCI-CTC Version 3.0 and presented as preferred terms MedDRA version 10.1.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including **Boxed WARNING**.

DOSING

Recommended ELITEK dosing: 0.2 mg/kg once daily¹

 <p>30-minute intravenous infusion</p>	 <p>For up to 5 days</p>	 <p>No dose modification requirement</p>
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- Not indicated for dosing beyond 5 days or administration of more than one course
- Do not administer as an intravenous bolus

ELITEK is available in 2 vial sizes: 1.5 mg and 7.5 mg¹

How supplied

- ELITEK 1.5 mg: 3 single-dose vials each containing 1.5 mg of rasburicase and 3 ampules each containing 1 mL diluent
- ELITEK 7.5 mg: 1 single-dose vial containing 7.5 mg of rasburicase and 1 ampule containing 5 mL diluent



Important Safety Information, cont'd

- Among the 275 adult patients in Study 4, hypersensitivity reactions occurred in 4.3% of patients treated with ELITEK alone and 1.1% of patients treated with the ELITEK plus oral allopurinol. Hypersensitivity reactions included arthralgia, injection site irritation, peripheral edema, and rash. The most common Grade 3-4 ARs regardless of relationship to study drug in Study 4 (ELITEK alone; ELITEK plus oral allopurinol; oral allopurinol alone) were sepsis (5.4%; 6.5%; 4.4%), hypophosphatemia (4.3%; 6.5%; 6.6%), anxiety (3.3%; 0%; 0%), abdominal pain (3.3%; 4.3%; 2.2%), hyperbilirubinemia (3.3%; 2.2%; 4.4%), and increased alanine aminotransferase (3.3%; 4.3%; 2.2%), respectively.

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PREPARATION AND ADMINISTRATION



How to prepare¹

- ELITEK must be reconstituted with the diluent provided in the carton
 - Reconstitute the 1.5-mg vial of ELITEK with 1 mL of diluent OR
 - Reconstitute the 7.5-mg vial of ELITEK with 5 mL of diluent
- Mix by swirling gently. **DO NOT SHAKE OR VORTEX**
- Inspect the vial of ELITEK and the diluent before administration, and discard if particulate matter or discoloration is visible



How to administer¹

- **ADMINISTER ELITEK AS AN INTRAVENOUS INFUSION ONLY**
- Inject the calculated dose of reconstituted ELITEK solution into an infusion bag containing the appropriate volume of 0.9% sterile sodium chloride, to achieve a final total volume of 50 mL. DO NOT use filters during infusion of reconstituted ELITEK drug product
- Infuse over 30 minutes through a separate IV line or flush line with at least 15 mL of normal saline prior to and after ELITEK infusion



Storing ELITEK¹

- Store reconstituted or diluted solution at 2°C-8°C (36°F-46°F)
- Discard unused product solution 24 hours following reconstitution
- The lyophilized drug product and the diluent for reconstitution should be stored at 2°C-8°C (36°F-46°F)
- Do not freeze
- Protect from light

Important Safety Information, cont'd

- The following serious ARs occurred with a difference in incidence of $\geq 2\%$ in patients receiving ELITEK vs. oral allopurinol in Study 1 and Study 4: pulmonary hemorrhage, respiratory failure, supraventricular arrhythmias, ischemic coronary artery disorders, and abdominal and gastrointestinal infections.



BILLING AND CODING

Product codes

ELITEK may be identified by a Healthcare Common Procedure Coding System (HCPCS) Level II code, National Drug Code (NDC), and a Current Procedural Terminology (CPT) code.

The coding information provided below is for informational purposes only.

HCPCS Level II code	
J2783	Injection, rasburicase, 0.5 mg for hospital inpatient, physician office and most payers
NDC codes	
0024-5150-10	ELITEK is supplied in a carton with 3 single-use vials each containing 1.5 mg of rasburicase and 3 ampules each containing 1 mL diluent
0024-5151-75	ELITEK is supplied in a carton with 1 single-use vial containing 7.5 mg of rasburicase and 1 ampule containing 5 mL diluent
CPT code administration in a physician's office	
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis; (specify substance of drug); initial, up to 1 hour

Hospital inpatient			Hospital outpatient	
Administration of ELITEK	Revenue code	0260 IV therapy, general	Revenue code	0260 IV therapy, general
	ICD-10 Procedure code	3E033GC Introduction of other therapeutic substance into peripheral vein, percutaneous approach	ICD-10 Procedure code	3E033GC Introduction of other therapeutic substance into peripheral vein, percutaneous approach
ELITEK	Revenue code	0250 Pharmacy, general	Revenue code	0636 Drugs requiring detailed coding

Important Safety Information, cont'd

WARNING: HYPERSENSITIVITY REACTIONS, HEMOLYSIS, METHEMOGLOBINEMIA, AND INTERFERENCE WITH URIC ACID MEASUREMENTS

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BILLING AND CODING CONT'D

Diagnosis codes

ICD-10	Description
C00.0-D49.9	Malignant neoplasm of external upper lip – Neoplasm of unspecified behavior of unspecified site
C82.90-C82.98	Follicular lymphoma, unspecified, unspecified site – Follicular lymphoma, unspecified, lymph nodes of multiple sites
C83.10-C83.18	Mantle cell lymphoma, unspecified site – Mantle cell lymphoma, lymph nodes of multiple sites
C83.30-C83.38	Diffuse large B-cell lymphoma, unspecified site – Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39-C83.38	Diffuse large B-cell lymphoma, extranodal and solid organ sites – Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.50-C83.58	Lymphoblastic (diffuse) lymphoma, unspecified site – Lymphoblastic (diffuse) lymphoma, lymph nodes of multiple sites
C83.70-C83.78	Burkitt's lymphoma, unspecified site – Burkitt's lymphoma, lymph nodes of multiple sites
C83.80-C83.88	Other non-follicular lymphoma, unspecified site – Other non-follicular lymphoma, lymph nodes of multiple sites
C84.40-C84.48	Peripheral T-cell lymphoma, not classified, unspecified site – Peripheral T-cell lymphoma, not classified, lymph nodes of multiple sites
C84.60-C84.68	Anaplastic large cell lymphoma, ALK-positive, unspecified site – Anaplastic large cell lymphoma, ALK-positive, lymph nodes of multiple sites
C85.80-C85.88	Other specified types of non-Hodgkin lymphoma, unspecified site – Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C90.10-C90.12	Plasma cell leukemia not having achieved remission – Plasma cell leukemia, in relapse
C91.00-C91.02	Acute lymphoblastic leukemia not having achieved remission – Acute lymphoblastic leukemia, in relapse
C91.10-C91.12	Chronic lymphocytic leukemia of B-cell type not having achieved remission – Chronic lymphocytic leukemia of B-cell type, in relapse
C91.Z0-C91.Z2	Other lymphoid leukemia not having achieved remission – Other lymphoid leukemia, in relapse
C91.40	Hairy cell leukemia not having achieved remission

Important Safety Information, cont'd

- **Hemolysis: Do not administer ELITEK to patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Immediately and permanently discontinue ELITEK in patients developing hemolysis. Screen patients at higher risk for G6PD deficiency (e.g., patients of African or Mediterranean ancestry) prior to starting ELITEK.**

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BILLING AND CODING CONT'D

Diagnosis codes (cont'd)

ICD-10	Description
C91.90-C91.92	Lymphoid leukemia, unspecified not having achieved remission – Lymphoid leukemia, unspecified, in relapse
C92.00-C92.02	Acute myeloblastic leukemia, not having achieved remission – Acute myeloblastic leukemia, in relapse
C92.10-C92.12	Chronic myeloid leukemia BCR/ABL-positive, not having achieved remission – Chronic myeloid leukemia BCR/ABL-positive, in relapse
C92.20-C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission – Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C92.Z0-C92.Z2	Other myeloid leukemia, not having achieved remission – Other myeloid leukemia, in relapse
C92.90-C92.92	Myeloid leukemia, unspecified, not having achieved remission – Myeloid leukemia, unspecified, in relapse
C93.00-C93.02	Acute monoblastic/monocytic leukemia, not having achieved remission – Acute monoblastic/monocytic leukemia, in relapse
C93.10-C93.12	Chronic myelomonocytic leukemia not having achieved remission – Chronic myelomonocytic leukemia, in relapse
C93.90-C93.92	Monocytic leukemia, unspecified, not having achieved remission – Monocytic leukemia, unspecified, in relapse
C93.Z0-C93.Z2	Other monocytic leukemia, not having achieved remission – Other monocytic leukemia, in relapse
C94.20-C94.22	Acute megakaryoblastic leukemia, not having achieved remission – Acute megakaryoblastic leukemia, in relapse
C94.30-C94.82	Mast cell leukemia, not having achieved remission – Other specified leukemias, in relapse
C95.00-C95.02	Acute leukemia of unspecified cell type, not having achieved remission – Acute leukemia of unspecified cell type, in relapse
C95.10-C95.12	Chronic leukemia of unspecified cell type, not having achieved remission – Chronic leukemia of unspecified cell type, in relapse
C95.90-C95.92	Leukemia, unspecified, not having achieved remission – Leukemia, unspecified, in relapse
C96.4-C96.9	Sarcoma of dendritic cells (accessory cells) – Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
E88.3	Tumor lysis syndrome

Important Safety Information, cont'd

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IMPORTANT SAFETY INFORMATION

CONT'D



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References: 1. ELITEK [prescribing information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; 2017. 2. Cortes J, Moore JO, Maziarz RT, et al. Control of plasma uric acid in adults at risk for tumor lysis syndrome: efficacy and safety of rasburicase alone and rasburicase followed by allopurinol compared with allopurinol alone—results of a multicenter phase III study. *J Clin Oncol.* 2010;28(27):4207-4213. 3. Jaki-Razumovi J, Aurer I. The World Health Organization classification of lymphomas. *Croat Med J.* 2002;43(5):527-534. 4. Nicolaides C, Dimou S, Pavlidis N. Prognostic factors in aggressive non-Hodgkin's lymphomas. *Oncologist.* 1998;3(3):189-197. 5. Howard SC, Jones DP, Pui C-H. The tumor lysis syndrome. *N Engl J Med.* 2011;364(19):1844-1854. 6. Data on file. Bridgewater, NJ: sanofi-aventis U.S. LLC. 7. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphomas. V.2.2019. ©National Comprehensive Cancer Network, Inc. 2018. All rights reserved. Accessed October 19, 2018. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. 8. Ueng S. Rasburicase (Elitek): a novel agent for tumor lysis syndrome. *Proc (Bayl Univ Med Cent).* 2005;18(3):275-279. 9. Coiffier B, Altman A, Pui C-H, Younes A, Cairo MS. Guidelines for the management of pediatric and adult tumor lysis syndrome: an evidence-based review. *J Clin Oncol.* 2008;26(16):2767-2778.