ELITEK®
rasburicase
IV Infusion

Clinician's Guide

The only FDA-approved recombinant urate-oxidase for the initial management of uric acid in patients with leukemia and lymphoma who are receiving anticancer therapy[1]

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 prechilled tubes containing heparin and immediately immerse and maintain sample in an ice water bath. Assay plasma samples within 4 hours of collection.**

Please see Important Safety Information throughout, and accompanying full Prescribing Information including Boxed WARNING.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

ELITEK is contraindicated in patients with a history of anaphylaxis or severe hypersensitivity to rasburicase or in patients with development of hemolytic reactions or methemoglobinemia with rasburicase. ELITEK is contraindicated in individuals deficient in glucose-6-phosphate dehydrogenase (G6PD).

ELITEK® rasburicase IV Infusion

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TLS=tumor lysis syndrome.

Please see Important Safety Information throughout, and accompanying full Prescribing Information including Boxed WARNING.

TLS: an oncologic emergency with **potentially devastating consequences**

TLS is caused by a massive release of intracellular contents into peripheral blood that results in metabolic derangements[2]

Hyperuricemia | Hyperkalemia | Hyperphosphatemia | Hypocalcemia

TLS may be prevalent in hematologic malignancies with[2]:

- High proliferative rate
- Large cellular burden
- High sensitivity to chemotherapy or cytolytic antibody therapy

TLS occurs spontaneously or in response to anticancer therapy, usually 12 to 72 hours after the start of therapy[2,3]

Various factors increase the risk of developing TLS[3-5]

- Bulky disease
- Lymph node involvement
- Bone marrow involvement
- Elevated WBC count
- High tumor burden
- Renal disease or renal involvement by tumor
- Elevated uric acid levels at baseline

This is not a comprehensive list of all potential risk factors.

TLS associated with hyperuricemia may lead to serious clinical complications[3]

WBC=white blood cell.

Laboratory and clinical **symptoms of TLS**

Cairo-Bishop classification of TLS[6]

Laboratory TLS

A patient with 2 or more of the following abnormalities within 3 days before to 7 days after initiation of cancer treatment:

- Uric acid ≥8 mg/dL or 25% increase from baseline
- Potassium ≥6 mEq/dL or 25% increase from baseline
- Phosphate ≥6.5 mg/dL (children), ≥4.5 mg/dL (adults), or 25% increase from baseline
- Calcium ≥25% decrease from baseline

Clinical TLS

A patient with laboratory TLS and at least 1 of the following:

- Creatine ≥1.5x the upper limit of normal (≥12 years of age or age adjusted)
- Cardiac arrhythmia
- Sudden death
- Seizure

ULN=upper limit of normal.

Certain anticancer agents have been associated with **elevated uric acid or TLS**[7-31]

Agents treating hematologic malignancies associated with risk of increasing uric acid or TLS[7-31]*

- Venetoclax
- Imatinib
- Dasatinib
- Nilotinib
- Ivosidenib
- Ibrutinib
- Obinutuzumab
- Rituximab†
- Carfilzomib
- Blinatumomab
- Axicabtagene ciloleucel
- Lenalidomide
- Thalidomide
- Pomalidomide
- Brentuximab vedotin
- Bortezomib
- Bendamustine HCl‡
- Vincristine sulfate†
- Doxorubicin HCl†
- Ixazomib
- Romidepsin
- Polatuzumab vedotin-piiq
- Tisagenlecleucel

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend TLS prophylaxis and monitoring based on tumor burden in patients with CLL/SLL receiving venetoclax[4]

- Manage patients with CrCl <80 mL/min and medium tumor burden (any lymph node 5 cm to <10 cm or ALC ≥25 x 10^9/L) as high risk for TLS
- Consider rasburicase for patients with both high tumor burden and elevated baseline uric acid§

NCCN Guidelines®

NCCN Clinical Practice Guidelines in Oncology for CLL/SLL: Consider prophylaxis with rasburicase in patients receiving venetoclax with high tumor burden and elevated baseline uric acid[4]

Please refer to venetoclax package insert for additional management considerations.

*This is not a comprehensive list of drugs that may be associated with TLS.

†Components of the R-CHOP regimen.

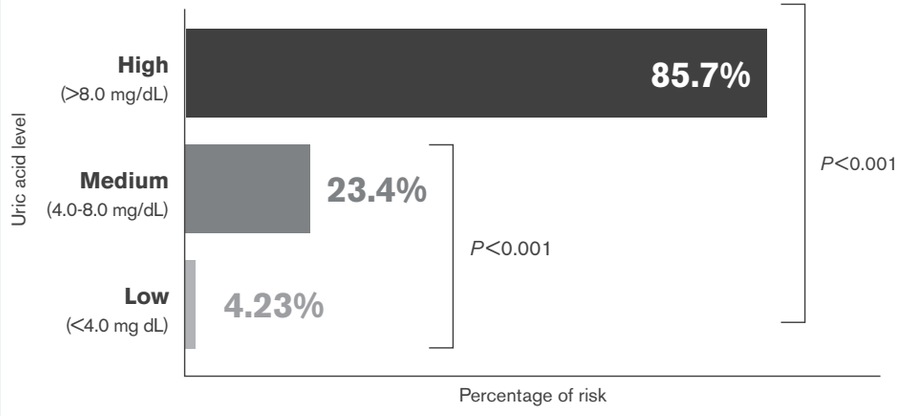
‡There is an increased risk of severe skin toxicity when bendamustine HCl is used concomitantly with allopurinol.

§In patients receiving venetoclax therapy, high tumor burden is defined as any lymph node ≥10 cm or ALC ≥25 x10^9/L and any lymph node ≥5 cm.

ALC=absolute lymphocyte count; CrCl=creatinine clearance; CLL=chronic lymphocytic leukemia; NCCN=National Comprehensive Cancer Network; SLL=small lymphocytic lymphoma.

Patients with normal uric acid levels may be at **significant risk**[32]

Relationship between uric acid level and development of TLS in patients with hematologic malignancies[32¶]



¶Results from a retrospective analysis conducted to determine the relationship between uric acid levels and TLS in 1198 patients with a hematologic malignancy who were admitted for inpatient chemotherapy.

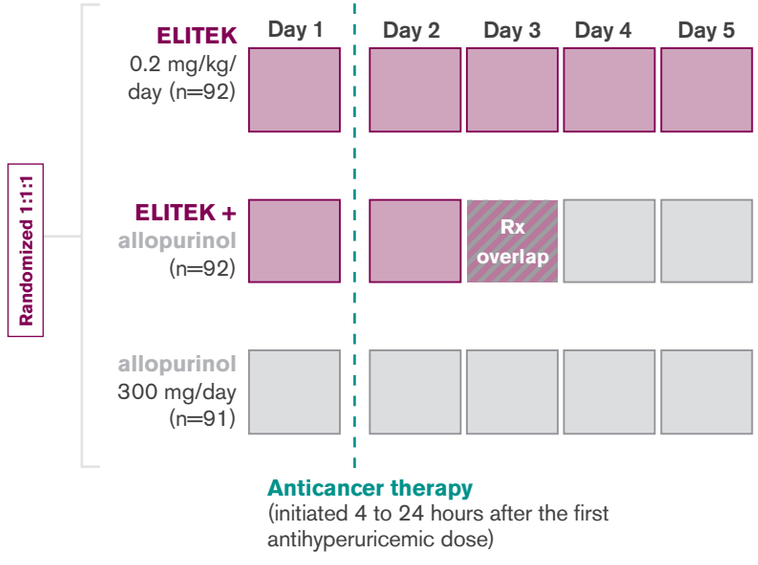
Not all patients who are at risk for TLS have elevated uric acid levels before starting anticancer therapy[6]

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:** randomized, multicenter, open-label study in adult patients (n=275) with leukemia, lymphoma, and solid tumor malignancies at risk for hyperuricemia and TLS
- **Primary endpoint:** response rate defined as the proportion of adult patients with plasma uric acid levels maintained at ≤7.5 mg/dL between 3 and 7 days after initiation of antihyperuricemic treatment

Adult pivotal trial design[1,2]



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

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥20%), when used concomitantly with anticancer therapy, are vomiting, nausea, fever, peripheral edema, anxiety, headache, abdominal pain, constipation, diarrhea, hypophosphatemia, pharyngolaryngeal pain, and increased alanine aminotransferase.

Baseline TLS risk

A majority of patients studied were at high risk for TLS associated with hyperuricemia but had normal uric acid levels at baseline[2]

92%
of adult patients were at high risk for TLS at baseline[2]

82%
of adult patients had normal uric acid levels (≤7.5 mg/dL) at baseline[2]

Adult patients meeting at least 1 of the following criteria were enrolled in the pivotal trial[2]:

High risk[2,33,34]	Intermediate (potential) risk[2]
Aggressive lymphoma/leukemia (defined by REAL) • 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 ≥2x the upper limit of normal
AML	Any stage III to IV aggressive lymphoma or leukemia
Elevated plasma uric acid levels (>7.5 mg/dL) at baseline	
High-grade MDS with >10% bone marrow blast involvement	Stage I or II aggressive disease with bulky lymph node/tumor (>5 cm) involvement
CML in blast crisis	

ELITEK is recommended for patients at high risk for development of TLS associated with hyperuricemia based on the Guidelines for the Management of Pediatric and Adult TLS[35]

AML=acute myeloid 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.

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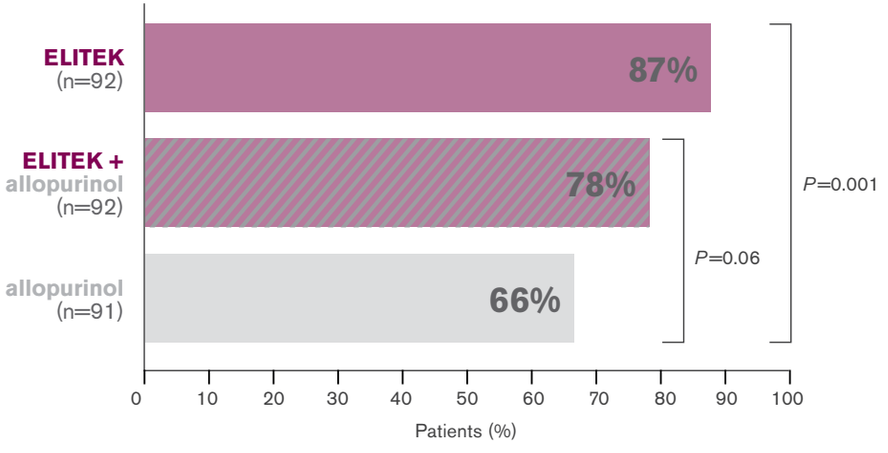
Efficacy in **adult patients**

ELITEK given prophylactically maintained normal uric acid levels in significantly more adult patients vs allopurinol[2]

Proportion of patients with normal uric acid levels ≤7.5 mg/dL from Day 3 to Day 7 after initiating antihyperuricemic treatment (primary endpoint)[2]



NCCN Guidelines®

NCCN Clinical Practice Guidelines in Oncology recommend that to best manage TLS, anticipate it and initiate treatment prior to anticancer therapy for patients with CLL/SLL and B-cell lymphoma[3,4]

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Consider the benefits and risks of ELITEK and possible risks to the fetus when prescribing ELITEK to a pregnant woman
- **Lactation:** Because of the potential for serious adverse reactions in the breastfed child, advise patients that breastfeeding is not recommended during treatment with ELITEK and for 2 weeks after the last dose

Documented failure rate

ELITEK maintained normal uric acid levels in 100% of assessable adult patients, unlike allopurinol[1]

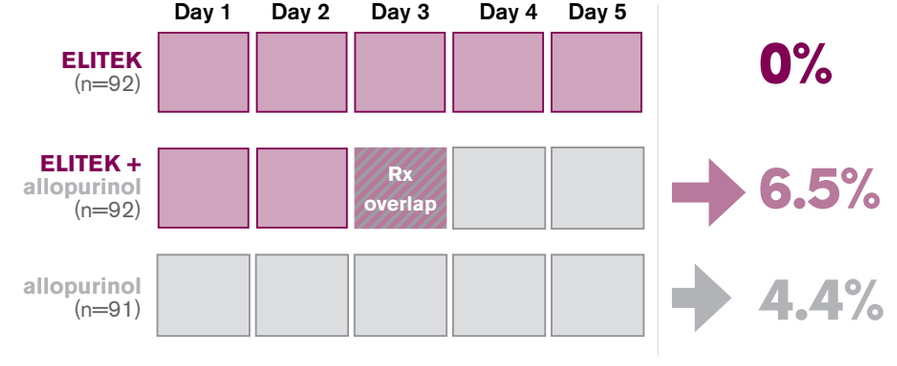
Documented failure rate in hyperuricemic and nonhyperuricemic adult patients[1]

ELITEK (n=92)	ELITEK + allopurinol (n=92)	allopurinol (n=91)
0%	0%	11%

- The ELITEK, ELITEK + allopurinol, and allopurinol arms had 13%, 15%, and 19% missing uric acid samples, respectively. The uric acid failure status in those patients is unknown[1]

No adult patients receiving ELITEK alone required antihyperuricemic treatment past 5 days[1]

Percentage of patients requiring antihyperuricemic treatment past 5 days[1]



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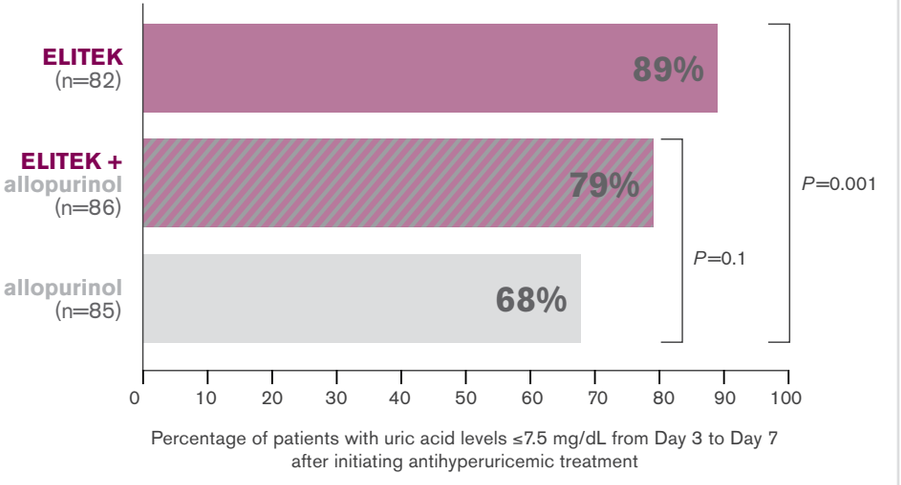
Efficacy in **high-risk adult patients**

ELITEK given prophylactically maintained normal uric acid levels in significantly more high-risk adult patients vs allopurinol[2]

High-risk patients (%) who maintained normal uric acid levels (≤7.5 mg/dL)[2,36]



Efficacy in **hyperuricemic adult patients**

ELITEK given prophylactically maintained normal uric acid levels in significantly more adult patients with baseline hyperuricemia vs allopurinol[2]

90% of adult patients with baseline hyperuricemia maintained normal uric acid levels (≤7.5 mg/dL from Day 3 to Day 7 after initiating antihyperuricemic treatment) with ELITEK (n=19) vs 53% with allopurinol alone (n=17) (*P*=0.015), while 77% maintained normal uric acid levels with ELITEK + allopurinol (n=13) (*P*=0.2)[2,36]

- 18% of adult patients (n=275) were hyperuricemic (>7.5 mg/dL) at baseline and therefore were considered at high risk of developing TLS[2]

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

ELITEK is contraindicated in patients with a history of anaphylaxis or severe hypersensitivity to rasburicase or in patients with development of hemolytic reactions or methemoglobinemia with rasburicase. ELITEK is contraindicated in individuals deficient in glucose-6-phosphate dehydrogenase (G6PD).

Adverse reactions

ELITEK has a proven safety profile[1]

Per-patient incidence of selected adverse reactions in Study 4[1]

	ELITEK % (n=92)		ELITEK + allopurinol % (n=92)		allopurinol % (n=91)	
ADVERSE REACTION*	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 of adverse reactions ≥10% in any ELITEK arm and the difference between any ELITEK arm vs the allopurinol arm ≥5%

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

ALT=alanine aminotransferase; NCI-CTC=National Cancer Institute-Common Terminology Criteria.

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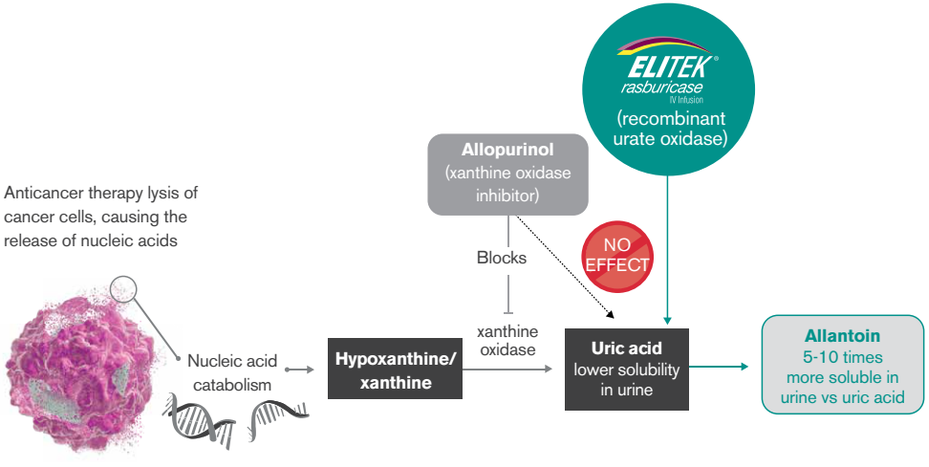
Mechanism of action

Unlike allopurinol, ELITEK clears new and existing uric acid[37]

For patients with cancer, ELITEK is the only antihyperuricemic agent that has the mechanism to clear existing uric acid[37]

- Allopurinol blocks the formation of new uric acid but has no mechanism to clear uric acid

Mechanism of action: ELITEK vs allopurinol[37,38]

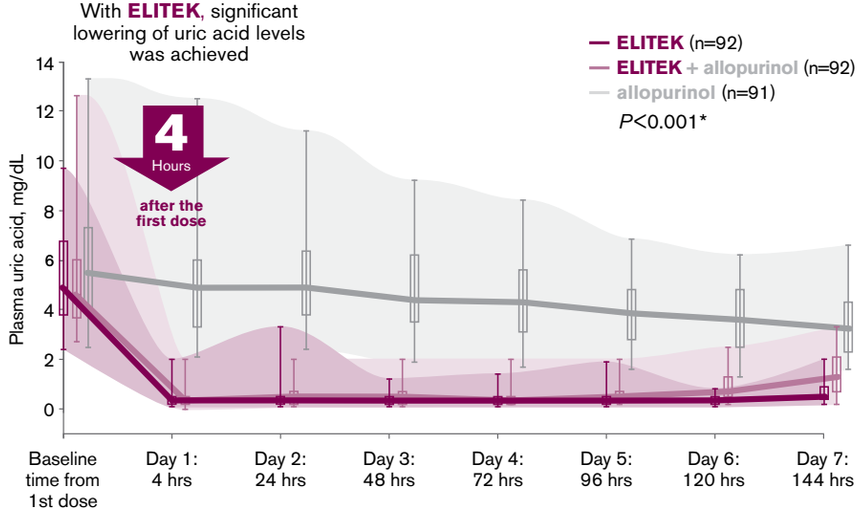


ELITEK significantly and rapidly **lowered uric acid levels compared with allopurinol[1,2]**

96%

of adult patients who received ELITEK achieved uric acid levels ≤2 mg/dL within 4 hours after their first dose vs 0% with allopurinol[1,2]

Reduction in uric acid levels[1,2]



*Plasma uric acid AUC from Day 1 through Day 7 was significantly lower for ELITEK and ELITEK + allopurinol than for allopurinol alone.

AUC=area under the curve.

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IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥20%), when used concomitantly with anticancer therapy, are vomiting, nausea, fever, peripheral edema, anxiety, headache, abdominal pain, constipation, diarrhea, hypophosphatemia, pharyngolaryngeal pain, and increased alanine aminotransferase.

ELITEK® rasburicase IV Infusion

Dosing

Recommended ELITEK dosing: 0.2 mg/kg once daily[1]

30-minute intravenous infusion

For up to 5 days

No dose-modification requirement

- Not indicated for dosing beyond 5 days or administration of more than 1 course
- Do not administer as an intravenous bolus

ELITEK is available in 2 vial sizes: 1.5 mg and 7.5 mg[1]

How supplied[1]

- 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

NDC# 0024-5150-10

ELITEK 1.5-mg kit

NDC# 0024-5151-75

ELITEK 7.5-mg kit

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Consider the benefits and risks of ELITEK and possible risks to the fetus when prescribing ELITEK to a pregnant woman
- **Lactation:** Because of the potential for serious adverse reactions in the breastfed child, advise patients that breastfeeding is not recommended during treatment with ELITEK and for 2 weeks after the last dose

Preparation and administration

How to prepare ELITEK[1]

- 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 administer ELITEK in all patients[1]

- **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 ELITEK[1]

- 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

Laboratory test interference

At room temperature, ELITEK causes enzymatic degradation of the uric acid in blood/plasma/serum samples potentially resulting in spuriously low plasma uric acid assay readings. The following special sample handling procedure must be followed to avoid ex vivo uric acid degradation:

- Uric acid must be analyzed in plasma
- Blood must be collected into prechilled tubes containing heparin anticoagulant
- Immediately immerse plasma samples for uric acid measurement in an ice water bath
- Plasma samples must be prepared by centrifugation in a precooled centrifuge (4°C)
- The plasma must be maintained in an ice water bath and analyzed for uric acid within 4 hours of collection

Explore the additional educational resources offered for ELITEK by visiting ELITEKpro.com

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ELITEK® rasburicase IV Infusion

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

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

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Diagnosis codes

ICD-10	Description
E79.0	Hyperuricemia without signs of inflammatory arthritis and tophaceous disease
E88.3	Tumor lysis syndrome
C00.0-D49.9	Neoplasms
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 lymphoma, unspecified site – Burkitt 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

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ELITEK® rasburicase IV Infusion

Billing and coding

Diagnosis codes (cont'd)

ICD-10	Description
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
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

IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

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Diagnosis codes (cont'd)

ICD-10	Description
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

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IMPORTANT SAFETY INFORMATION

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- **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 prechilled tubes containing heparin and immediately immerse and maintain sample in an ice water bath. Assay plasma samples within 4 hours of collection.**

CONTRAINDICATIONS

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ADVERSE REACTIONS

Most common adverse reactions (incidence ≥20%), when used concomitantly with anticancer therapy, are vomiting, nausea, fever, peripheral edema, anxiety, headache, abdominal pain, constipation, diarrhea, hypophosphatemia, pharyngolaryngeal pain, and increased alanine aminotransferase.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Consider the benefits and risks of ELITEK and possible risks to the fetus when prescribing ELITEK to a pregnant woman
- **Lactation:** Because of the potential for serious adverse reactions in the breastfed child, advise patients that breastfeeding is not recommended during treatment with ELITEK and for 2 weeks after the last dose

Please see accompanying full Prescribing Information, including Boxed WARNING.

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IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

ELITEK is contraindicated in patients with a history of anaphylaxis or severe hypersensitivity to rasburicase or in patients with development of hemolytic reactions or methemoglobinemia with rasburicase. ELITEK is contraindicated in individuals deficient in glucose-6-phosphate dehydrogenase (G6PD).

Please see Important Safety Information throughout, and accompanying full Prescribing Information including Boxed WARNING.

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MAT-US-2101189-v1.0-03/2021