ELITEK® rasburicase IV Infusion

# 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 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 additional Important Safety Information throughout and full Prescribing Information, including Boxed WARNING.**

# TABLE OF CONTENTS



TLS=tumor lysis syndrome

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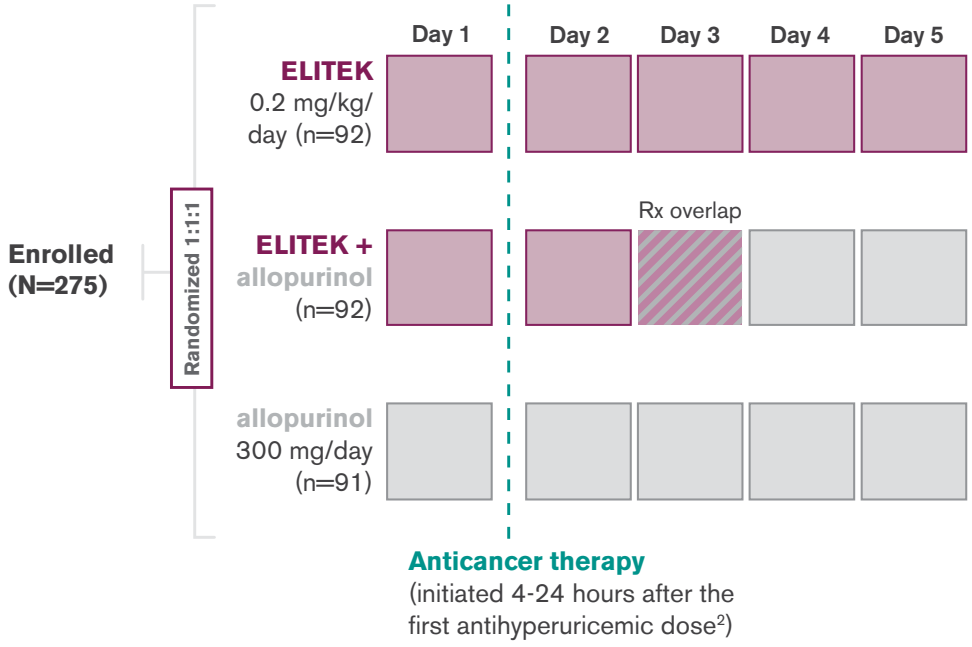
# TRIAL DESIGN

## 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

**Pivotal trial design[1,2]**




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

## 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).

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# BASELINE TLS RISK

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

**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 trial:[2]

| High risk[2-4] | Intermediate (potential) risk[2] |
|---|---|
| Aggressive lymphoma/leukemia (defined by REAL)<br>• DLBCL<br>• Anaplastic large cell lymphoma<br>• Peripheral T-cell lymphomas<br>• Burkitt lymphoma<br>• Lymphoblastic lymphoma<br>• CLL | Aggressive lymphoma/leukemia, not limited to the REAL definition, with LDH ≥2x the upper limit of normal |
| AML | Any stage III to IV lymphoma or leukemia |
| Elevated plasma uric acid levels at baseline (>7.5mg/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.

## 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.

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# RESULTS IN HIGH-RISK PATIENTS

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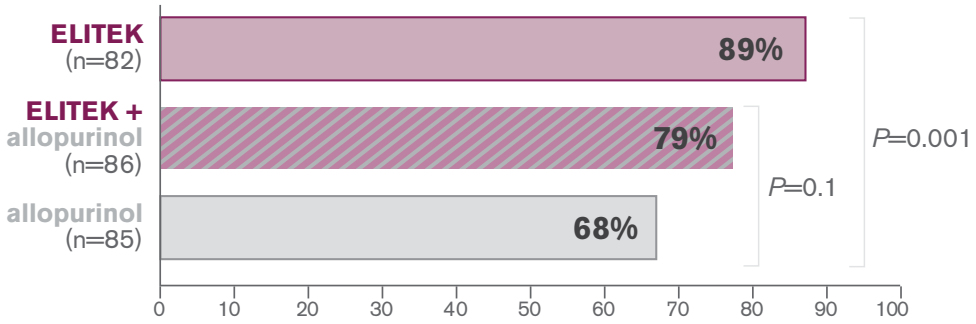
## ELITEK given prophylactically maintained normal uric acid levels ≤7.5 mg/dL in significantly more high-risk patients vs allopurinol[2]

**High-risk patients (%) who maintained normal uric acid levels (≤7.5 mg/dL)[2,6]**




Percentage of patients with uric acid levels ≤7.5 mg/dL from Day 3 to Day 7 after initiating antihyperuricemic treatment

- 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]

**ELITEK is recommended for patients at high and intermediate (potential) risk for development of TLS associated with hyperuricemia[5]**

## 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.

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# DOCUMENTED FAILURE RATE

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

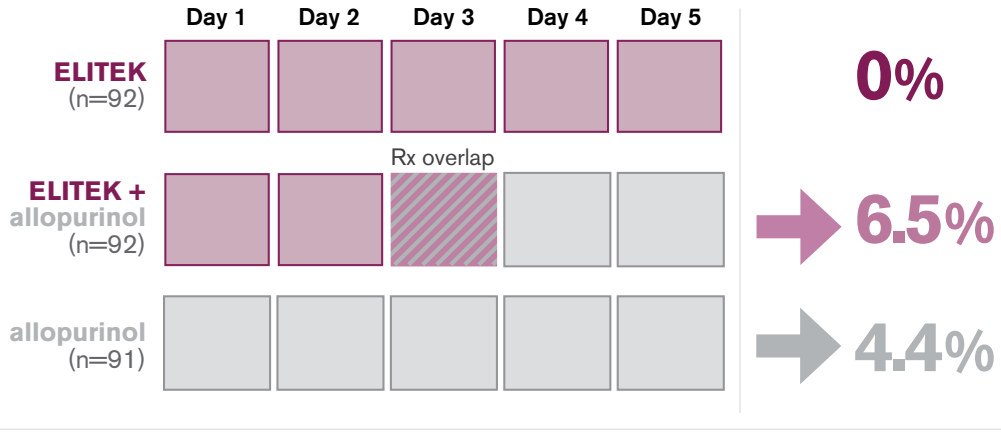
**Documented failure rate in hyperuricemic and nonhyperuricemic patients[1]**

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

- 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]

## Unlike allopurinol, no patients receiving ELITEK required antihyperuricemic treatment beyond 5 days[1]

**Percent of patients requiring antihyperuricemic treatment past 5 days[1]**




## Important Safety Information, cont'd

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

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# RESULTS IN PATIENTS WITH HYPERURICEMIA BASELINE

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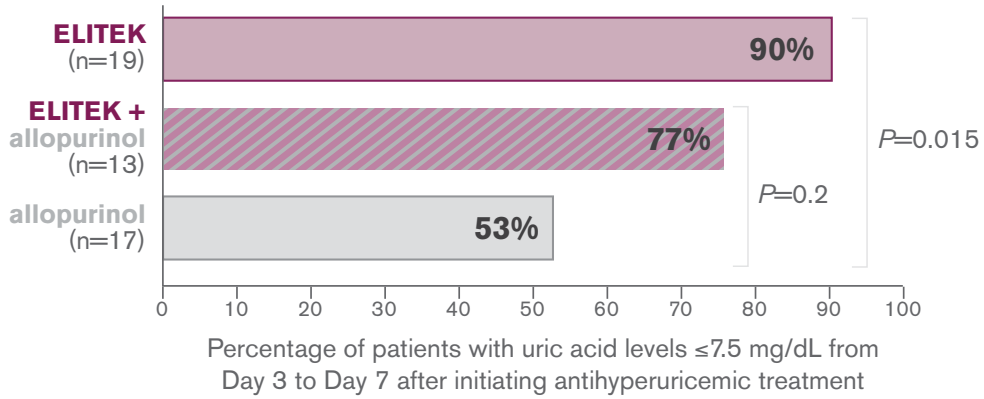
## ELITEK given prophylactically maintained normal uric acid levels ≤7.5 mg/dL in significantly more patients with hyperuricemia at baseline vs allopurinol[2]

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

**Hyperuricemic patients (%) who maintained normal uric acid levels (≤7.5 mg/dL)[2,6]**

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  - 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 acid[7]**

SLL=small lymphocytic lymphoma.

## Important Safety Information, cont'd

- **Methemoglobinemia: ELITEK can result in methemoglobinemia in some patients. Immediately and permanently discontinue ELITEK in patients developing methemoglobinemia.**
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# URIC ACID REDUCTION IN PIVOTAL TRIAL

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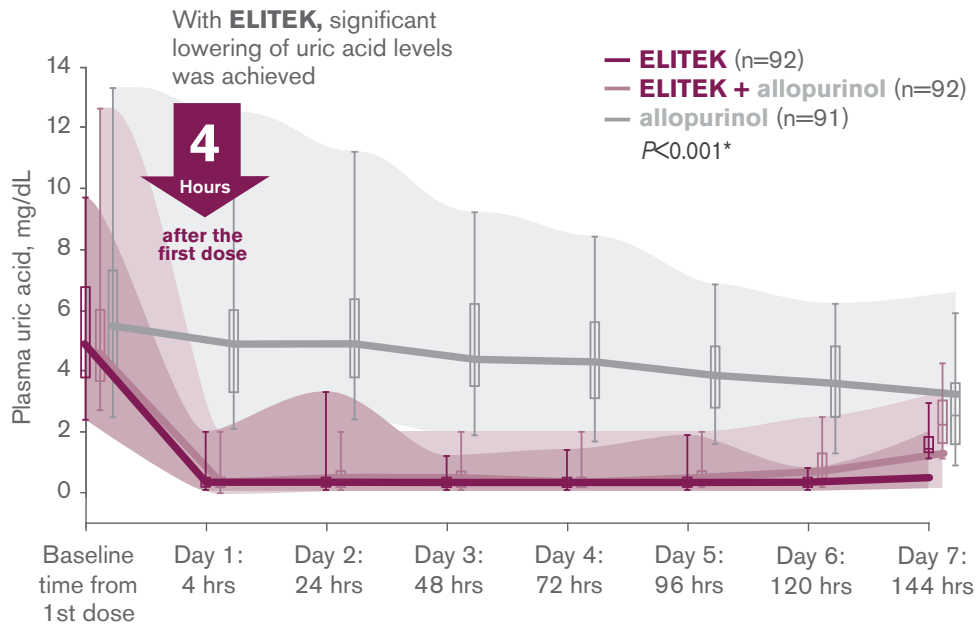
## ELITEK given prophylactically significantly and rapidly lowered uric acid levels[1,2]

**96%** of ELITEK patients 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 ($P<0.001$).

## Important Safety Information, cont'd

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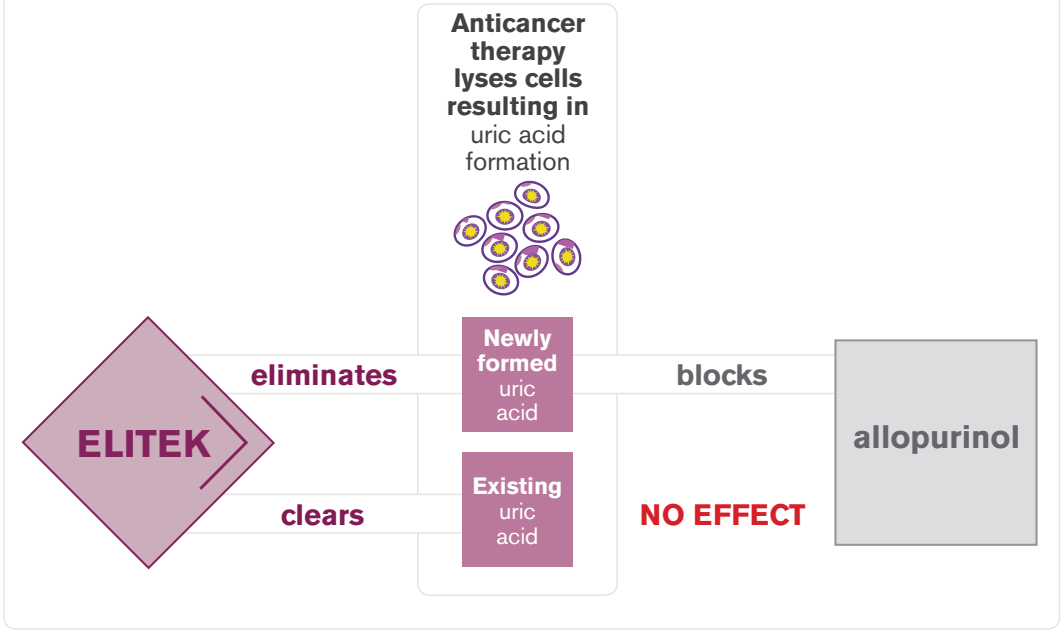
# MECHANISM OF ACTION

## Unlike allopurinol, ELITEK clears new and existing uric acid[8]

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

**Mechanism of action: ELITEK vs allopurinol[8,9]**




## Important Safety Information, cont'd

**CONTRAINDICATIONS**

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# ADVERSE REACTIONS

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## ELITEK has a proven safety profile[1]

**Per-patient incidence of selected adverse reactions[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 ≥10% in any ELITEK arm and the difference between any ELITEK arm vs allopurinol ≥5%.[1]

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

- **Hypersensitivity reactions occurred in 4.3% of ELITEK-treated patients and 1.1% of ELITEK/allopurinol treated patients in Study 4. Clinical manifestations of hypersensitivity included arthralgia, injection site irritation, peripheral edema, and rash.**
- **The following serious adverse reactions occurred at a difference in incidence of ≥2% in patients receiving ELITEK compared to patients receiving allopurinol in randomized studies (Study 1 and Study 4): pulmonary hemorrhage, respiratory failure, supraventricular arrhythmias, ischemic coronary artery disorders, and abdominal and gastrointestinal infections.**
- **The incidence of anaphylaxis, hemolysis, and methemoglobinemia was less than 1% of the 887 ELITEK treated patients entered on the clinical trials.**

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# DOSING

ELITEK® rasburicase IV Infusion

## 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 one course
- Do not administer as an intravenous bolus

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


**ELITEK 1.5 mg**

**NDC# 0024-5150-10**

3 single-dose vials each containing 1.5 mg of ELITEK and 3 ampules each containing 1 mL diluent


**ELITEK 7.5 mg**

**NDC# 0024-5151-75**

1 single-dose vial containing 7.5 mg of ELITEK and 1 ampule containing 5 mL diluent

## 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.

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# PREPARATION AND ADMINISTRATION

ELITEK® rasburicase IV Infusion

## How to prepare[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[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

## 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.

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# BILLING AND CODING

ELITEK® rasburicase IV Infusion

## 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

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# BILLING AND CODING CONT'D

ELITEK® rasburicase IV Infusion

## 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 |
| C90.00 | Multiple myeloma not having achieved remission |
| 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

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# BILLING AND CODING CONT'D

ELITEK® rasburicase IV Infusion

## 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 |
| E79.0 | Hyperuricemia without signs of inflammatory arthritis and tophaceous disease |
| E88.3 | Tumor lysis syndrome |

## Important Safety Information, cont'd

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# PATIENT RESOURCES AND SUPPORT

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CareASSIST™ Patient Support by Sanofi Genzyme

CareASSIST is a support program designed to help eligible patients get access to prescribed Sanofi Genzyme therapies.

- **Access and Reimbursement:** Assistance navigating the insurance process, including benefits investigations, claims assistance, and information about prior authorizations and appeals.
- **Financial Assistance:** CareASSIST offers programs and services that can help eligible patients with the cost of ELITEK.
  - Eligible patients with commercial insurance may qualify for the CareASSIST Copay Program and may pay as little as **$0 out of pocket** for ELITEK
  - Eligible patients with no insurance, or who lack coverage, may qualify for the CareASSIST Patient Assistance Program and receive ELITEK **at no cost**
- **Resource Support:** Information on independent support services for patients and caregivers, as well as product ordering and replacement information.

**Tap into support for ELITEK today!**

Call **1.833.WE+CARE (1.833.930.2273)**
Monday through Friday, 9am to 8pm ET

Visit **SanofiCareAssist.com/hcp/ELITEK** for more information

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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 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 full Prescribing Information, including Boxed WARNING.**

**References: 1.** ELITEK [prescribing information]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC. **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.** Jakic´-Razumovic´ 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.


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