ELITEK® rasburicase IV Infusion

PRODUCT INFORMATION

Product Information

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
QTY/Units per Case	24 cartons / case
NDC Codes	0024-5150-10 (1.5 mg) 0024-5151-75 (7.5 mg)
HCPCS Level II Code	J2783 – Injection, rasburicase, 0.5 mg for hospital inpatient, physician office and most payers
CPT Code	96365

Storage and Handling

- The lyophilized drug product and the diluent for reconstitution should be stored at 2-8°C (36-46°F).[1]
- Do not freeze.[1]
- Protect from light.[1]

Distributors and Pharmacies

Please reach out to your preferred distributors to obtain ELITEK for patients.

To learn more about ELITEK

- Visit **ELITEKpro.com**
- Call **800-633-1610** for medical inquiries
- Contact your **Sanofi Genzyme representative**

Indication

ELITEK is indicated for the initial management of plasma uric acid levels in pediatric and adult 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

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.

Please see additional Important Safety Information on the following page and full Prescribing Information, including boxed WARNING.

ELITEK®
rasburicase
IV Infusion

Important Safety Information cont'd

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

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.

- 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 (≥10%) were vomiting (50%), fever (46%), nausea (27%), headache (26%), abdominal pain (20%), constipation (20%), diarrhea (20%), mucositis (15%), and rash (13%).
- 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 amino-transferase (3.3%; 4.3%; 2.2%), respectively.
- The following serious ARs occurred with a difference in incidence of > 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

Please see full Prescribing Information, including boxed WARNING.

Reference: 1. ELITEK [prescribing information]. Bridgewater, NJ: sanofi-aventis U.S. LLC; 2017.

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