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.

Patient Resources and Support

- CareASSIST is a support program designed to help eligible patients get access to prescribed Sanofi Genzyme therapies. If your patients have commercial insurance, they 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 medication **at no cost**
- Call **833-WE+CARE (833-930-2273)**, Monday-Friday, 9 AM – 8 PM EST
- Visit **SanofiCareAssist.com/hcp/ELITEK**

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

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.**

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

To learn more about ELITEK

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

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.**
- **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

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

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 full Prescribing Information, including Boxed WARNING.

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

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