

ELITEK[®] is indicated for the initial management of plasma uric acid levels in pediatric 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.

Special Plasma Handling Instructions for Patients Initiated With *ELITEK*

Uric Acid Measurement Precautions

- 1 To avoid *ex vivo* uric acid degradation, thereby ensuring accurate measurements, special plasma sample handling procedures **must** be followed
- 2 At room temperature, *ELITEK* causes enzymatic degradation of the uric acid in blood samples, resulting in spuriously low plasma uric acid assay readings

Laboratory Sample Handling Procedures

- 1 Collect blood samples using pre-chilled tubes containing **heparin** anticoagulant
- 2 **Immediately** immerse and maintain blood samples in an **ice water bath**
- 3 Prepare plasma samples using centrifugation in a pre-cooled centrifuge (4°C)
- 4 Analyze the plasma sample for uric acid within **4 hours** of collection while maintaining the sample in an **ice water bath**

To order, please contact your wholesaler. For product information, contact your sales representative or call 1-800-446-6267.

ELITEK[®]
rasburicase IV Infusion

BOXED WARNINGS: **Anaphylaxis:** *ELITEK* may cause severe hypersensitivity reactions including anaphylaxis. *ELITEK* should be immediately and permanently discontinued in any patient developing clinical evidence of a serious hypersensitivity reaction. **Hemolysis:** *ELITEK* administered to patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency can cause severe hemolysis. *ELITEK* administration should be immediately and permanently discontinued in any patient developing hemolysis. It is recommended that patients at higher risk for G6PD deficiency (eg, patients of African or Mediterranean ancestry) be screened prior to starting *ELITEK* therapy. **Methemoglobinemia:** *ELITEK* use has been associated with methemoglobinemia. *ELITEK* administration should be immediately and permanently discontinued in any patient identified as having developed methemoglobinemia. **Interference With Uric Acid Measurements:** *ELITEK* will cause enzymatic degradation of the uric acid within blood samples left at room temperature, resulting in spuriously low uric acid levels. To ensure accurate measurements, blood must be collected into prechilled tubes containing heparin anticoagulant and immediately immersed and maintained in an ice water bath; plasma samples must be assayed within 4 hours of sample collection.

Important Safety Information: Among the 703 patients for whom serious adverse reactions were assessed, the most serious adverse reactions caused by *ELITEK* were allergic reactions including anaphylaxis (<1%), rash (1%), hemolysis (<1%), and methemoglobinemia (<1%). The commonly observed adverse events were fever (5%), neutropenia with fever (4%), respiratory distress (3%), sepsis (3%), neutropenia (2%), and mucositis (2%). Among the 347 patients for whom all adverse reactions regardless of severity were assessed, the most frequently observed adverse reactions (incidence $\geq 10\%$) 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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Please see accompanying full Prescribing Information including Boxed Warnings.