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Rx CARE

New approved drug one of few tested mostly in children

The Food & Drug Administration has approved rasburicase (Elitek, Sanofi-Synthelabo), one of the few drugs tested in clinical studies involving predominantly pediatric patients. Said Susannah Koontz, Pharm.D., BCOP, clinical practice specialist, pediatric hematology and oncology, M. D. Anderson Cancer Center, Houston, "This is one drug for which we have a substantial amount of data collected in children."

Rasburicase is indicated for the initial management of plasma uric acid levels in pediatric patients with leukemia, lymphoma, and solid tumor malignancies who are receiving therapies that may result in tumor lysis and subsequent elevation in plasma uric acid levels. "Rasburicase is indicated as an adjunctive therapy for the prevention of tumor lysis syndrome," said Koontz. "It does not prevent tumor lysis syndrome from occurring."

Rasburicase fascilitates the enzymatic oxidation of uric acid to allantoin, which is five to 10 times more soluble in urine than uric acid, Koontz explained. The body can excrete allantoin faster and more effectively than uric acid.

According to Koontz, patients whose tumors have a high turnover rate, such as those with leukemia and lymphoma, or patients with a high tumor burden, as in those with certain types of lymphomas, are candidates for rasburicase therapy. A few patients with solid tumors, such as those with testicular or metastatic breast cancer, may also be candidates for treatment with the drug, she added. "It was mainly tested in patients with a hematological malignancy, however," she said.

Rasburicase is contraindicated in patients with a glucose-6- phosphate dehydrogenase (G6PD) deficiency, because of a risk of hemolysis, said Koontz. Rasburicase is also contraindicated in patients with a history of anaphylaxis or hypersensitivity reactions, she

said, and its use should be discontinued in patients presenting with clinical evidence of a hypersensitivity reaction. According to the prescribing information (PI), rasburicase is associated with methemoglobinemia, and its use should be discontinued in patients who have developed methemoglobinemia. The PI contains boxed warnings about the risk of hemolysis, anaphylaxis, and methemoglobinemia.

The PI states that rasburicase is classified as a pregnancy category C and should be administered to a pregnant or breast-feeding woman only if absolutely necessary. Insufficient data exist to determine whether older persons, or adults in general, will respond differently from pediatric patients to rasburicase therapy, according to the PI. Adverse effects associated with rasburicase in clinical trials include vomiting, fever, nausea, and headache.

The recommended dosage, said Koontz, is .15 or .20 mg/kg q.d. for five days administered as an IV infusion over 30 minutes. "For patients with very high tumor burden, such as those with Burkitt's lymphoma, I would recommend giving it every 12 hours for the first day or two," said Stanton Goldman, M.D., pediatric hematologist/ oncologist, North Texas Hospital for Children, Dallas. As stated in the PI, chemotherapy should be initiated four to 24 hours after the first dose of rasburicase is given.

Charlotte LoBuono

TIPS TO REMEMBER: Elitek

- Magnesium, phosphorus, and potassium levels must be monitored in patients taking Elitek. Additionally, monitoring blood pressure, urine output, and hydration is important. Creatinine, plasma uric acid, and lactate dehydrogenase levels should also be monitored in these persons.
- A boxed warning in the labeling states that Elitek will cause the enzymatic degradation of uric acid in blood samples stored at room temperature. Blood must be collected into pre-chilled tubes, immediately transferred to an ice water bath, and then processed within four hours of collection.

Charlotte LoBuono. New approved drug one of few tested mostly in children. *Drug Topics* 2002;16:12.