SERB Pharmaceuticals

VORAXAZE® (glucarpidase)
1000 units/vial for intravenous injection

You're Invited to Breakfast on Friday, April 25, 2025

Join Us to Learn More about Treatment Options for Patients Experiencing High-Dose Methotrexate-Induced Acute Kidney Injury

Date: Friday, April 25, 2025 **Breakfast:** 7:30am-8:15am **Location:** Six Continents Room

What you will learn during this presentation:

- **Importance of Early Recognition of HDMTX-Induced AKI**
- **Why dialysis may not be the best treatment option for reducing plasma MTX Levels[1]**
- **A monitoring tool, MTXPK.org, to help identify if your patient is clearing MTX as expected[2]**
- **How Early Voraxaze Use can lead to improved Clinical and Economic Outcomes[3]**
- **Newly Published Data on Adult Patients Experiencing HDMTX-AKI**
- **Evaluate clinical data on re-challenging HDMTX following Voraxaze Treatment[4,5]**
- **Voraxaze Replacement Policy**

Presenter:

Jaya Kala, MD

Associate Professor,
Chief Onco-Nephrology
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This program is developed and offered by SERB Pharmaceuticals.
This is not an official program of the Cleveland Clinic.

INDICATIONS AND LIMITATIONS OF USE

- Voraxaze® is a carboxypeptidase indicated to reduce toxic plasma methotrexate concentration (greater than 1 micromole per liter) in adult and pediatric patients with delayed methotrexate clearance (plasma methotrexate concentrations greater than 2 standard deviations of the mean methotrexate excretion curve specific for the dose of methotrexate administered) due to impaired renal function
- Limitations of Use: Voraxaze® is not recommended for use in patients who exhibit the expected clearance and expected plasma methotrexate concentration. Reducing plasma methotrexate concentration in these patients may result in subtherapeutic exposure to methotrexate

WARNINGS AND PRECAUTIONS

Serious Hypersensitivity Reactions

- Serious hypersensitivity reactions, including anaphylactic reactions, may occur. Serious hypersensitivity reactions occurred in less than 1% of patients

Monitoring Methotrexate Concentration/Interference With Assay

- Methotrexate concentrations within 48 hours following Voraxaze® administration can only be reliably measured by a chromatographic method due to interference from metabolites. Measurement of methotrexate concentrations within 48 hours of Voraxaze® administration using immunoassays results in an overestimation of the methotrexate concentration

ADVERSE REACTIONS

- In clinical trials, the most common related adverse events (occurring in >1% of patients) were paresthesia, flushing, nausea and/or vomiting, hypotension and headache

DRUG INTERACTIONS

- Voraxaze® can decrease leucovorin concentration, which may decrease the effect of leucovorin rescue unless leucovorin is dosed as recommended, and may also reduce the concentrations other folate analogs or folate analog metabolic inhibitors

References

1. Ghannoum M et al. Clin J Am Soc Nephrol. 2022;17(4):602-622. 2; 2. Taylor ZL, Mizuno T, Punt NC, et al. Clin Pharmacol Ther. 2020;108(3):635-643; 3. Kala J et al. Clinicoecon Outcomes Res. 2023;15:165-179; 4. Christensen AM et al. Cancer. 2012;118(17):4321-4330; 5. Truong HL et al. JCO Oncol Pract. 2024;00:1-11.

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Voraxaze Full Prescribing Information