SELENIOUS ACID INJECTION, for intravenous use

Initial U.S. Approval: 2019

INDICATIONS AND USAGE
Selenious Acid Injection is a trace element indicated in adult and pediatric patients as a source of selenium for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated. (1)

DOSAGE AND ADMINISTRATION
Full prescribing information for all added components to determine the recommended nutritional requirements for dextrose, amino acids and lipid emulsion, as applicable. (2.4, 2.5)

- Prior to administration of PN solution containing Selenious Acid Injection, correct severe fluid, electrolyte and acid-base disorders.

- Use Selenious Acid Injection for admixing promptly once the sterile transfer set has been inserted into the Pharmacy Bulk Package Container.

- Use PN solution containing Selenious Acid Injection promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a brief period of time, no longer than 24 hours. After admixing, and prior to administration. The solution should be clear and there should be no precipitates. A slight yellow color does not alter the affinity and efficacy of this product.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Monitor Selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Monitor Selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Monitor Selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Use Selenious Acid Injection for admixing promptly once the sterile transfer set has been inserted into the Pharmacy Bulk Package Container.

- Use PN solution containing Selenious Acid Injection promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a brief period of time, no longer than 24 hours. After admixing, and prior to administration. The solution should be clear and there should be no precipitates. A slight yellow color does not alter the affinity and efficacy of this product.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Use Selenious Acid Injection for admixing promptly once the sterile transfer set has been inserted into the Pharmacy Bulk Package Container.

- Use PN solution containing Selenious Acid Injection promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a brief period of time, no longer than 24 hours. After admixing, and prior to administration. The solution should be clear and there should be no precipitates. A slight yellow color does not alter the affinity and efficacy of this product.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Use Selenious Acid Injection for admixing promptly once the sterile transfer set has been inserted into the Pharmacy Bulk Package Container.

- Use PN solution containing Selenious Acid Injection promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a brief period of time, no longer than 24 hours. After admixing, and prior to administration. The solution should be clear and there should be no precipitates. A slight yellow color does not alter the affinity and efficacy of this product.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Use Selenious Acid Injection for admixing promptly once the sterile transfer set has been inserted into the Pharmacy Bulk Package Container.

- Use PN solution containing Selenious Acid Injection promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a brief period of time, no longer than 24 hours. After admixing, and prior to administration. The solution should be clear and there should be no precipitates. A slight yellow color does not alter the affinity and efficacy of this product.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Use Selenious Acid Injection for admixing promptly once the sterile transfer set has been inserted into the Pharmacy Bulk Package Container.

- Use PN solution containing Selenious Acid Injection promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a brief period of time, no longer than 24 hours. After admixing, and prior to administration. The solution should be clear and there should be no precipitates. A slight yellow color does not alter the affinity and efficacy of this product.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.

- Use Selenious Acid Injection for admixing promptly once the sterile transfer set has been inserted into the Pharmacy Bulk Package Container.

- Use PN solution containing Selenious Acid Injection promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a brief period of time, no longer than 24 hours. After admixing, and prior to administration. The solution should be clear and there should be no precipitates. A slight yellow color does not alter the affinity and efficacy of this product.

- Monitor selenium concentrations during treatment. Selenium concentrations may vary depending on the assay used and the laboratory reference range. The lower end of the range reported in healthy adults is 7 to 10 mcg/dL.
Selenious Acid has a molecular weight of 128.97 g/mol and a formula of H$_2$SeO$_3$.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Selenious acid is converted in vivo to hydrogen selenide via glutathione-involved electron reductions. Hydrogen selenide acts as a selenium pool to form selenoproteins which include, but are not limited to, glutathione peroxidase, iodothyronine deiodinase, peroxidase and thioredoxins.

12.2 Pharmacodynamics
Selenious Acid exposure-response relationships and the time course of pharmacodynamic responses is unknown.

12.3 Pharmacokinetics

Distribution
In humans 85% of intravenous administered $^{75}$Se was protein-bound within 4 to 6 hours and 95% by 24 hours. Elimination
Selenium is primarily eliminated in urine.

16 HOW SUPPLIED/STORAGE AND HANDLING
Selenious Acid Injection, USP is a clear, colorless solution available as 600 mcg/10mL (60 mcg/mL) of selenium in a 10 mL Pharmacy Bulk Package vial. Carton of 5 vials (NDC 00517-8569-05) Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]
For storage of admixed solution, see Dosage and Administration (2.3).

17 PATIENT COUNSELING INFORMATION
Inform patients, caregivers or home healthcare providers of the following risks of Selenious Acid Injection:
- Pulmonary embolism due to pulmonary vascular precipitates [see Warnings and Precautions (5.1)].
- Vein damage and thrombosis [see Warnings and Precautions (5.2)].
- Aluminum toxicity [see Warnings and Precautions (5.3)].

AMERICAN REGENT, INC.
SHIRLEY, NY 11967
IN6560
Rev. 07/2019