Selenious Acid
Injection, USP

PRODUCT INFORMATION BULLETIN

Selenious Acid Injection, USP, is the first FDA-approved 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] Selenious Acid, available in a 600 mcg/10 mL (60 mcg/mL) pharmacy bulk package vial, is not for direct intravenous infusion; it is for *admixing use only*.

Aligns with Current Treatment Guidelines

- Selenious Acid Injection aligns with the American Society for Parenteral and Enteral Nutrition (ASPEN) recommendations for trace element supplementation[2]
- ASPEN recommends the parenteral selenium intake in adults should be 60–100 mcg/day, and 2 mcg/kg/day for pediatric patients weighing up to 40 kg[2]

Proven Stability

- Stability studies support that Selenious Acid Injection can be safely stored for up to 9 days when added to the parenteral nutrition admixture and refrigerated[1]
  - Discard any unused portion of the pharmacy bulk package vial within 4 hours after initial closure puncture

Consistent Supply

- Selenious Acid Injection is proudly manufactured in America. American Regent is committed to providing a consistent supply to help ensure that your patient care needs are met

Selenious Acid Injection, USP, aligns with the daily recommendations for parenteral trace elements set forth by ASPEN.[1,2]

Population	ASPEN Recommended Requirement[2]
Preterm Neonate	2 mcg/kg/day
Term Neonate 3–10 kg	2 mcg/kg/day
Children 10–40 kg	2 mcg/kg/day (max 100 mcg/day)
Adolescents < 40 kg	40-60 mcg/day
Adults	60-100 mcg/day

Population	Selenious Acid Injection Recommended Dosage[1]
Pediatric Patients weighing less than 7 kg	2 to 4 mcg/kg/day
Pediatric Patients weighing 7 kg and above	2 mcg/kg/day (up to 60 mcg/day)
Adults	60 mcg/day

Selenious Acid Injection provides 60 mcg/mL of selenium. The dosage of Selenious Acid Injection should be individualized based on the patient's clinical condition, nutritional requirements, and the contribution of oral or enteral selenium intake. The dosages are general recommendations intended for most patients. However, based on clinical requirements, some patients may require a higher dosage. Please see full precribing information for complete dosing information.

For intravenous use

INDICATIONS AND USAGE

Selenious Acid Injection is 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.

Important Administration Information

Selenious Acid Injection is supplied as a pharmacy bulk package for admixing use only. It is *not for direct intravenous infusion.*

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None

WARNINGS AND PRECAUTIONS

Pulmonary Embolism due to Pulmonary Vascular Precipitates: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation.

Vein Damage and Thrombosis: Selenious Acid Injection has a low pH and must be prepared and used as an admixture in PN solutions. Solutions with osmolarity of 900 mOsm/L or more must be infused through a central venous catheter.

Aluminum Toxicity: Selenious Acid Injection contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Preterm infants are particularly at risk for aluminum toxicity because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which also contain aluminum.

Monitoring and Laboratory Tests: Monitor selenium concentrations, fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters throughout treatment.

ADVERSE REACTIONS

No selenium-related adverse reactions have been reported in clinical studies or postmarketing reports in patients receiving intravenously administered PN solutions containing selenious acid within the recommended dosage range.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary: Administration of the recommended dose of Selenious Acid Injection in PN is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation: Risk Summary: Selenium is present in human milk. There is no information on the effects of selenious acid on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Selenious Acid Injection and any potential adverse effects on the breastfed infant from Selenious Acid Injection or from the underlying maternal condition.

Pediatric Use: Safety and dosing recommendations in pediatric patients are based on clinical experience.

Geriatric Use: Dose selection should be individualized based on the patient's clinical condition, nutritional requirements, and additional nutritional intake provided orally or enterally to the patient.

For additional safety information, please see the Full Prescribing Information.

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You are encouraged to report Adverse Drug Events (ADEs) to American Regent:
T 1.800.734.9236; **E** pv@americanregent.com; **F** 1.610.650.0170

ADEs may also be reported to the FDA:
1.800.FDA.1088
or to www.fda.gov/medwatch

Medical Information: 1.888.354.4855

For medical information outside of normal business hours (9:00 am – 5:00 pm Eastern Time, Monday – Friday) that cannot wait until the next business day, please call 1.877.845.6371

References

1. Selenious Acid Injection [package insert]. Shirley, NY: American Regent, Inc. 10/2020
2. American Society for Parenteral and Enteral Nutrition (ASPEN) website:
http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-FINAL.pdf. Accessed December 4, 2020.

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