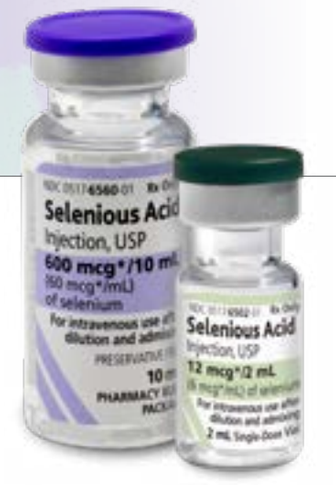

# Selenious Acid
Injection, USP




## Introducing Selenious Acid Injection, USP in a new concentration and vial size

The Selenious Acid family now includes a 12 mcg/2 mL (6 mcg/mL) single-dose vial designed for pediatric and neonatal patients and a 600 mcg/10 mL (60 mcg/mL) pharmacy bulk package. Both product sizes are for parenteral nutrition admixing use only—not for direct intravenous infusion.[1]

Selenious Acid Injection, USP is a trace element indicated for adult and pediatric patients as a source of selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.[1]

- **Designed to meet the needs of neonatal, pediatric, and adult patients**
  - New 12 mcg/2 mL (6 mcg/mL of selenium) concentration available for the treatment of neonatal and pediatric patients weighing less than 7 kg[1]
  - Also available in a 600 mcg/10 mL (60 mcg/mL of selenium) concentration for the treatment of adult and pediatric patients[1]
- **Aligns with current treatment guidelines**
  - Selenious Acid Injection, USP aligns with the American Society for Parenteral and Enteral Nutrition (ASPEN) Dosing Recommendations for trace elements supplementation[2]
  - ASPEN recommends that 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, USP can be safely stored for up to 9 days when added to the parenteral nutrition admixture and refrigerated[1]
  - Please immediately discard any unused drug from the single-dose vial. Please discard within 4 hours any unused drug from the pharmacy bulk package vial[1]
- **Consistent supply**
  - Selenious Acid Injection, USP is proudly manufactured in the US with active pharmaceutical ingredients and components sourced in the US. Our supply chain is short and less complicated. As a result, American Regent is uniquely positioned to provide you with supply consistency to help ensure critical medications reach patients faster

Please see the table below for product specifications. For additional information, please visit www.americanregent.com

## PRODUCT SPECIFICATIONS

| | Selenious Acid Injection, USP Single-dose vial | Selenious Acid Injection, USP Pharmacy bulk package vial |
|---|---|---|
| **Pack NDC** | 0517-6502-10 | 0517-6560-05 |
| **Strength** | 12 mcg/2 mL (6 mcg/mL) of selenium | 600 mcg/10 mL (60 mcg/mL) of selenium |
| **Concentration** | 6 mcg/mL | 60 mcg/mL |
| **Vial type** | Single-dose vial | Pharmacy bulk package vial |
| **Fill volume** | 2 mL | 10 mL |
| **Preservative** | No | No |
| **Specific gravity** | 1.000 g/mL | 1.000 g/mL |
| **Cap color** | Dark green | Purple |
| **Aluminum content** | No more than 900 mcg/L | No more than 2,500 mcg/L |
| **Pack size** | 10 | 5 |
| **Storage** | Store at 20°C-25°C (68°F-77°F) | Store at 20°C-25°C (68°F-77°F) |
| **Trace element stability in TPN** | Up to 9 days when added to the PN admixture and refrigerated | Up to 9 days when added to the PN admixture and refrigerated |

NDC=National Drug Code; PN=parenteral nutrition; TPN=total parenteral nutrition.

**Selenious Acid Injection, USP aligns with the daily recommendations set forth by ASPEN**

## DAILY RECOMMENDED DOSAGE OF SELENIOUS ACID INJECTION, USP BY ESTIMATED WEIGHT—NEONATAL, PEDIATRIC, AND ADULT PATIENTS

| ASPEN daily dosing requirements[2] | | American Regent daily dosing requirements[1] | |
|---|---|---|---|
| Preterm neonate | 2 mcg/kg/day | Pediatric patients less than 7 kg | 2 to 4 mcg/kg/day |
| Term neonate 3-10 kg | 2 mcg/kg/day | | |
| Children 10-40 kg | 2 mcg/kg/day (max 100 mcg/day) | Pediatric patients 7 kg and above | 2 mcg/kg/day (up to 60 mcg/day) |
| Adolescents >40 kg | 40-60 mcg/day | | |
| Adults | 60-100 mcg/day | Adults | 60 mcg/day |

**For complete information, including dosing and administration, please see the Full Prescribing Information.**

American Regent's multiple trace elements products may require supplementation with single trace elements such as Selenious Acid in certain patient groups. When using Selenious Acid Injection, USP with Tralement® (trace elements injection 4*, USP) or Multrys™ (trace elements injection 4*, USP), please see the respective product's Full Prescribing Information for appropriate dosing information.

*Each mL of Tralement contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg.
Each mL of Multrys contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg.

**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
Pharmacy Bulk Package or Single Dose Vial: *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 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 www.fda.gov/medwatch

**Medical information:**
**T** 1.888.354.4855
(9:00 am – 5:00 pm Eastern Time, Monday – Friday)
www.americanregent.com/medical-affairs

For medical information outside of normal business hours that cannot wait until the next business day, please call 1.877.845.6371

**REFERENCES:**

1. Selenious Acid Injection, USP [package insert]. Shirley, NY: American Regent, Inc. 8/2021.
2. American Society for Parenteral and Enteral Nutrition. Appropriate dosing for parenteral nutrition: ASPEN Recommendations. November 17, 2020. Accessed October 4, 2021. http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-FINAL.pdf

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