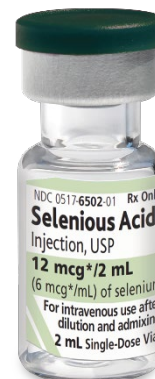




# American Regent announces the launch of Selenious Acid Injection, USP in a 12 mcg/2 mL single-dose vial.



Selenious Acid Injection, USP is now supplied in a 12 mcg/2 mL single-dose vial

Selenious Acid, in this new concentration and vial size has been specifically designed for pediatric and neonatal patients weighing less than 7 kg

**Melville, NY – March 31, 2022:** American Regent, Inc. is pleased to announce the launch of **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 of selenium) single-dose vial designed for pediatric and neonatal patients less than 7 kg.

Selenious Acid Injection is a trace element indicated in adult and pediatric patients as a source of selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.<sup>1</sup>

“We are pleased to add the 12 mcg/2 mL (6 mcg/mL) single-dose vial of Selenious Acid to our family of FDA-approved products. Both Selenious Acid products available from American Regent have been developed to align with the American Society for Parenteral and Enteral Nutrition (ASPEN) Dosing Recommendations for trace elements supplementation.<sup>2</sup> This launch demonstrates our continued commitment to the needs of special patient populations through the expansion of the Selenious Acid product line,” stated Joann Gioia, Vice President and Chief Commercial Officer at American Regent, Inc.

**This product is available for immediate shipment. Customers can order Selenious Acid Injection, USP through their wholesaler/distributor, or by contacting our Customer Support Group at 1-800-645-1706.**

Selenious Acid Injection, USP is supplied as follows:

Pack NDC#	Strength	Supplied as	Shelf pack
0517-6502-10	12 mcg/2 mL (6 mcg/mL of selenium)	2 mL Single-dose vial	10

See the following Important Safety Information, in addition to the product’s Full Prescribing Information. For additional information, please visit [www.americanregent.com](http://www.americanregent.com).

**REFERENCES:**

1. Selenious Acid Injection, USP [package insert]. Shirley, NY: American Regent, Inc. 2020
2. American Society for Parenteral and Enteral Nutrition. Appropriate dosing for parenteral nutrition: ASPEN Recommendations. November 17, 2020. Accessed October 22, 2021. [http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines\\_and\\_Clinical\\_Resources/PN%20Dosing%201-Sheet-FINAL.pdf](http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-FINAL.pdf)

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## 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 osmolality 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 osmolality, 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.

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For additional safety information, please see [Full Prescribing Information](#).

**You are encouraged to report adverse drug events (ADEs) to American Regent:**

**T** 1.800.734.9236; **E** [pv@americanregent.com](mailto: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](http://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](http://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

**About American Regent**

American Regent, Inc., a Daiichi Sankyo Group company, is a top-10 injectable manufacturer. For over 50 years, American Regent has been developing, manufacturing and supplying quality generic and branded injectables for healthcare providers. For nearly 20 years, we have been a leader in IV iron therapy.

American Regent is committed to US-based manufacturing. To that end, over the last several years, we have made significant investments in expanding and modernizing our manufacturing facilities in Ohio and New York. This expansion will nearly double our capacity and allow us to better serve our customers now and in the future.

Speed counts. Flexibility matters. Reliability and quality are paramount. Because patients should never have to wait for the medications they need.

For more information, please visit [www.americanregent.com](http://www.americanregent.com).

**About Daiichi Sankyo Group**

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders.

For more information, please visit: [www.daiichisankyo.com](http://www.daiichisankyo.com).

Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is a member of the Daiichi Sankyo Group.

For more information on Daiichi Sankyo, Inc., please visit [www.dsi.com](http://www.dsi.com).