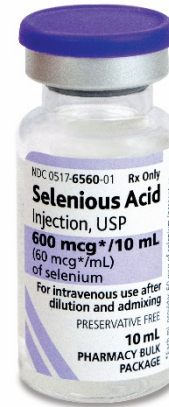




For Immediate Release

October 2, 2019

Gennine Kelly
Director of Marketing and Portfolio Management
American Regent, Inc.
corpcommunications@americanregent.com



Selenious Acid Injection, USP is supplied as a 10 mL pharmacy bulk package vial in a strength of 600 mcg/10 mL.

American Regent Announces the Availability of Selenious Acid Injection, USP in a 5-pack

Shirley, NY - American Regent is pleased to announce the availability of Selenious Acid Injection, USP in a new pack size of 5 (NDC# 0517-6560-05). The product will continue to be available in a pack of 25 (NDC# 0517-6560-25) while supplies last.

“We are pleased to offer the first FDA approved Selenious Acid Injection - developed to align with the American Society for Parenteral and Enteral Nutrition (ASPEN) recommendations for trace element supplementation.¹ This approval underscores our commitment to the parenteral nutrition market in the long term.” stated Harsher Singh, *Chief Commercial and Strategic Officer* at American Regent, Inc. In addition, the approved product will permit delivery of the recommended dose of Selenium in a smaller volume than the previously available marketed unapproved product.

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
0517-6560-05	600 mcg/10 mL (60 mcg/ mL)	10 mL Pharmacy Bulk Package Vial	5 (NEW)
0517-6560-25	600 mcg/10 mL (60 mcg/ mL)	10 mL Pharmacy Bulk Package Vial	25

See the following Important Safety Information in addition to the [Full Prescribing Information](#).

For additional information, please visit americanregent.com.

Reference: 1. Vanek et al. ASPEN position paper: recommendations for changes in commercially available parenteral multivitamin and multi-trace element products. *Nutr Clin Pract.* 2012 Aug; 27 (4):440-91.



SELENIOS ACID INJECTION, USP

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 [Full Prescribing Information](#).

REF-1167 6/2019

You are encouraged to report Adverse Drug Events (ADEs) to American Regent:

Email: pv@americanregent.com; **Fax:** 1-610-650-0170;

Phone: 1-800-734-9236

ADEs may also be reported to the FDA at 1-800-FDA-1088

or to www.fda.gov/Medwatch

Drug Information:

1-888-354-4855

(9:00 am – 5:00 pm Eastern Time, Monday – Friday)

For urgent drug information outside of normal business hours,
assistance is available at:

1-877-845-6371

About American Regent

American Regent, Inc. is a Daiichi Sankyo Group company with over \$1B in U.S. sales. American Regent develops, manufactures and supplies high-quality sterile injectables for healthcare providers and their patients.

Supporting patient health is the guiding principle of American Regent and our promise is to provide the healthcare marketplace with a steady supply and broad portfolio of branded and generic specialty injectables. We are a top-10 injectable supplier in therapeutic areas including IV additives, anti-inflammatories, diuretics, cytotoxics and diagnostic dyes. Additionally, for nearly 20 years, American Regent has been a leader in IV iron therapy and supplies two of the top-selling brands in the U.S. today.

For more information, please visit www.americanregent.com.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 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 hypertension and thrombotic disorders, under the Group’s 2025 Vision to become a “Global Pharma Innovator with Competitive Advantage in Oncology,” Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: 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.