Selenious Acid

Injection, USP

June 1, 2020

American Regent, Inc. is pleased to make available the first FDA approved **Selenious Acid Injection, USP**. This presentation was developed to be aligned with the American Society for Parenteral and Enteral Nutrition (ASPEN) recommendations for trace element supplementation. ASPEN recommends the parenteral selenium intake in adults should be 60–100 mcg/day and for pediatrics, 2 mcg/kg/day[1]. The strength and concentration of the FDA approved **Selenious Acid Injection, USP** will permit delivery of the recommended dose of selenium in a smaller volume as compared to the previously available marketed unapproved product. **Selenious Acid Injection, USP** will now be sold in a pack of 5 (NDC# 0517-6560-05). The product will be available in a pack of 25 (NDC# 0517-6560-25) while supplies last. See Full Prescribing Information for dosing and administration.

Selenious Acid Injection, USP is indicated as a source of selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated[2]. See Important Safety Information below.

Please review the table below detailing specifications and differences between the FDA approved product, and the previously available marketed unapproved product:

	MARKETED UNAPPROVED	NEW FDA APPROVED PRODUCT
MANUFACTURER	American Regent	American Regent
PACK NDC#	0517-6510-25	0517-6560-05, 0517-6560-25
PRODUCT NAME	Selenium Injection	Selenious Acid Injection, USP
STRENGTH	**400 mcg/10 mL** (40 mcg/mL)	**600 mcg/10 mL** (60 mcg/mL) of Selenium
VIAL TYPE	Single Dose Vial (SDV) - Glass	Pharmacy Bulk Package (PBP) Vial - Glass
FILL VOLUME	10 mL	10 mL
CAP COLOR	Orange	Purple
PRESERVATIVE	Preservative Free	Preservative Free
ACTIVE INGREDIENT	Selenious Acid	Selenious Acid
OTHER INGREDIENTS	Water for Injection	Water for Injection
ALUMINUM CONTENT	Contains no more than 2,500 mcg/L of aluminum	Contains no more than 2,500 mcg/L of aluminum
SHELF LIFE	24 Months	24 Months
PACK SIZE	25	5 and 25
STORAGE	20^{0}C –25^{0}C (68^{0}F–77^{0}F)	20^{0}C–25^{0}C (68^{0}F–77^{0}F)

Marketed Unapproved Product

New FDA Approved Product

If you have further questions, please contact the American Regent Customer Service team at **1-800-645-1706**.

REFERENCES

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.
2. Selenious Acid Injection [package insert]. Shirley, NY: American Regent, Inc. 2019

265 Broadhollow Road \\ 4th Floor \\ Melville, NY 11747

T 631.924.4000 \\ **F** 631.924.1731 \\ americanregent.com

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SELENIOUS 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.

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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., 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. In 2018, more than 99% of units supplied were manufactured in our US based facilities making us uniquely positioned to quickly mobilize to and respond to shortages or changes in market needs.

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 https://www.americanregent.com.

About Daiichi Sankyo
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/.

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.