American Regent Announces the Launch and Availability of Selenious Acid Injection, USP

NEWS PROVIDED BY
American Regent, Inc. →
Jul 10, 2019, 13:00 ET

SHIRLEY, N.Y., July 10, 2019 /PRNewswire/ -- American Regent today announced the introduction of Selenious Acid Injection, USP.

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

"We are pleased to offer the first FDA approved Selenious Acid Injection - developed to reflect 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 newly 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
0517-6560-25	**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.

PP-SB-US-0003 7/2019

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.

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 their promise is to provide the healthcare marketplace with a steady supply and broad portfolio of branded and generic specialty injectables. American Regent is 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

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