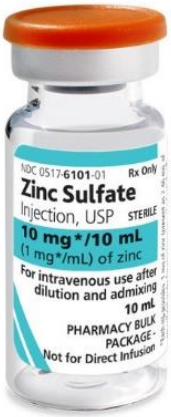
American Regent Introduces FDA Approved 10 mg/10 mL Zinc Sulfate Injection, USP



Zinc Sulfate Injection, USP, is supplied as a 10 mg/10 mL Pharmacy Bulk Package vial, in a carton of 25 vials. The strength is 1 mg/mL.

Shirley, NY–May 18, 2020: American Regent, Inc. has announced the addition of a new FDA approved 10 mg/10 mL (1 mg/mL) strength vial of Zinc Sulfate Injection, USP.[1] Zinc Sulfate is a trace element indicated in adult and pediatric patients as a source of zinc for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.[2]

"We are pleased to add the 10 mg/10 mL strength of Zinc Sulfate to our family of FDA approved Zinc Sulfate products. All three Zinc Sulfate Injection concentrations currently available from American Regent have been developed to align with the American Society for Parenteral and Enteral Nutrition (ASPEN) recommendations for trace element supplementation.[3] This launch demonstrates our continued commitment to addressing the FDA's safety initiative for unapproved products," [4]stated Harsher Singh, Vice President, Chief Commercial and Strategic Officer at American Regent, Inc.

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

The new Zinc Sulfate Injection, USP, is supplied as follows:

Pack NDC#	Strength	Supplied As	Shelf Pack
0517-6101-25	10 mg/10 mL (1 mg/mL)	10 mL Pharmacy Bulk Package Vial	25

See the following Important Safety Information, in addition to the product's Full Prescribing Information.

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

References

1. Approved Drug Products with Therapeutic Equivalence Evaluations: https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm Accessed April 20, 2020.
2. Zinc Sulfate Injection, USP [package insert]. Shirley, NY: American Regent, Inc. 2020.
3. American Society for Parenteral and Enteral Nutrition (ASPEN) website: http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-FINAL.pdf. Accessed April 20, 2020.
4. FDA's Concerns About Unapproved Drugs: https://www.fda.gov/drugs/unapproved-drugs/fdas-concerns-about-unapproved-drugs#main-content. Accessed April 20, 2020.

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ZINC SULFATE INJECTION, USP

For intravenous use

INDICATIONS AND USAGE

Zinc Sulfate is a trace element indicated in adult and pediatric patients as a source of zinc for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Zinc Sulfate Injection is supplied as a pharmacy bulk package for *admixing use* only. It is *not for direct intravenous infusion.*

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Zinc Sulfate Injection is contraindicated in patients with known hypersensitivity to zinc.

WARNINGS AND PRECAUTIONS

Pulmonary Embolism due to Pulmonary Vascular Precipitates: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation. The infusion set and catheter should be checked periodically for precipitates.

Vein Damage and Thrombosis: Zinc Sulfate 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: Zinc Sulfate 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 zinc concentrations, fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters throughout treatment.

Copper Deficiency: Several post-marketing cases have reported that high doses of supplemental zinc (approximately 10 times the recommended dosage of 3 mg/day Zinc Sulfate Injection in adults) taken over extended periods of time (i.e., months to years) may result in decreased enteral copper absorption and copper deficiency.

Hypersensitivity Reactions: If hypersensitivity reactions occur, discontinue Zinc Sulfate Injection and initiate appropriate medical treatment.

ADVERSE REACTIONS

No zinc-related adverse reactions have been reported in clinical studies or postmarketing reports in patients receiving intravenously administered PN solutions containing zinc sulfate within the recommended dosage range.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary: Administration of the recommended dose of Zinc Sulfate Injection in PN is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation: Risk Summary: Zinc is present in human milk. There is no information on the effects of zinc sulfate on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Zinc Sulfate Injection and any potential adverse effects on the breastfed infant from Zinc Sulfate Injection or from the underlying maternal condition.

Pediatric Use: Safety and dosing recommendations in pediatric patients are based on published literature describing controlled studies of zinc-containing products in pediatric patients.

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.

OVERDOSAGE: There are reported cases of overdosage with intravenous zinc in parenteral nutrition.

For additional safety information, please see Full Prescribing Information.

REF-1299 10/2019

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:
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 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 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.

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.