Zinc Sulfate
Injection, USP

PRODUCT INFORMATION BULLETIN

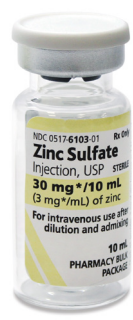
American Regent, Inc. is pleased to announce the **NEW FDA APPROVED Zinc Sulfate Injection, USP.**[1] Zinc Sulfate is a trace element indicated in adult and pediatric patients as a source of zinc for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.[2]

After spending considerable time, effort and resources, the new products (0517-6103-25 and 0517-8005-25) were developed to align with the American Society for Parenteral and Enteral Nutrition (ASPEN) recommendations for trace element supplementation.[3] The 3 mg/mL product represents a new concentration of Zinc Sulfate Injection, USP.

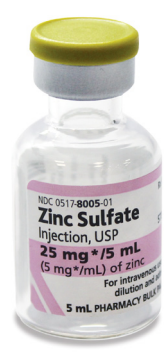
The new FDA approved Zinc Sulfate Injection, USP will replace the previously marketed, unapproved Zinc Sulfate Injection, USP. Please review the tables below for specifications on both the FDA approved Zinc Sulfate Injection, USP, and the previously available, marketed unapproved Zinc Sulfate Injection, USP:

AMERICAN REGENT	NEW FDA APPROVED PRODUCT	
PACK NDC#	**0517-6103-25**	**0517-8005-25**
GENERIC NAME	Zinc Sulfate Injection, USP	Zinc Sulfate Injection, USP
STRENGTH	30 mg/10 mL	25 mg/5 mL
CONCENTRATION	3 mg/mL	5 mg/mL
VIAL TYPE	Glass Pharmacy Bulk Package Vial	Glass Pharmacy Bulk Package Vial
FILL VOLUME	10 mL	5 mL
CAP COLOR	White	Mustard
PRESERVATIVE	Preservative Free	Preservative Free
ACTIVE INGREDIENT	3 mg of Zinc as 7.41 mg of Zinc Sulfate per mL	5 mg of Zinc as 12.32 mg of Zinc Sulfate per mL
OTHER INGREDIENT	Water for Injection	Water for Injection
ALUMINUM CONTENT	No more than 2,500 mcg/L of Aluminum	No more than 2,500 mcg/L of Aluminum
SHELF LIFE	24 months	24 months
PACK SIZE	25	25
STORAGE	Store at 20°C to 25°C (68°F to 77°F)	Store at 20°C to 25°C (68°F to 77°F)

0517-6103-25

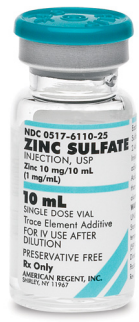


0517-8005-25



AMERICAN REGENT	PREVIOUSLY MARKETED UNAPPROVED PRODUCT	
PACK NDC#	**0517-6110-25**	**0517-8105-25**
GENERIC NAME	Zinc Sulfate Injection, USP	Concentrated Zinc Sulfate Injection, USP
STRENGTH	10 mg/10 mL	25 mg/5 mL
CONCENTRATION	1 mg/mL	5 mg/mL
VIAL TYPE	Glass Single Dose Vial	Glass Single Dose Vial
FILL VOLUME	10 mL	5 mL
CAP COLOR	Aqua	Aqua
PRESERVATIVE	Preservative Free	Preservative Free
ACTIVE INGREDIENT	1 mg of Zinc as 2.46 mg of Zinc Sulfate per mL	5 mg of Zinc as 12.32 mg of Zinc Sulfate per mL
OTHER INGREDIENT	Water for Injection	Water for Injection
ALUMINUM CONTENT	No more than 2,500 mcg/L of Aluminum	No more than 2,500 mcg/L of Aluminum
SHELF LIFE	24 months	24 months
PACK SIZE	25	25
STORAGE	Store at 20°C to 25°C (68°F to 77°F)	Store at 20°C to 25°C (68°F to 77°F)

0517-6110-25



0517-8105-25

As required, the previously available, marketed unapproved Zinc Sulfate will no longer be manufactured or distributed, and American Regent will ensure a smooth transition for customers to the new approved formulations as soon as they are available. All orders placed for the marketed, unapproved Zinc Sulfate products will be canceled in our system as of January 23, 2020.

PACK NDC#	ORDER DATE	SHIP DATE
MARKETED UNAPPROVED PRODUCT 0517-6110-25 0517-8105-25	**January 23, 2020** Last day orders will be accepted	**January 23, 2020** Last day orders will be fulfilled
NEW FDA APPROVED PRODUCT 0517-6103-25 0517-8005-25	**January 27, 2020** Orders will be accepted this day forward	**Week of February 3, 2020**

See the following Important Safety Information, in addition to the product's Full Prescribing Information. If you have further questions, please contact the American Regent Customer Service team at 1-800-645-1706.

You are encouraged to report Adverse Drug Events to American Regent, Inc. at 1-800-734-9236, or to the FDA by visiting www.fda.gov/medwatch, or by calling 1-800-FDA-1088.

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/results_product.cfm?Appl_Type=N&Appl_No=209377. Accessed November 26, 2019.
2. Zinc Sulfate Injection, USP [package insert]. Shirley, NY: American Regent, Inc. 2019
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 November 26, 2019.

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.

You are encouraged to report Adverse Drug Events to American Regent, Inc. at 1-800-734-9236, or to the FDA by visiting www.fda.gov/medwatch, or by calling 1-800-FDA-1088.

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. 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 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.

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