



Zinc Sulfate

Injection, USP

FREQUENTLY ASKED QUESTIONS

Pack NDC#	Strength	Supplied As	Shelf Pack
0517-6101-25	1 mg/mL	10 mL Pharmacy Bulk Package Vial	25
0517-6103-25	3 mg/mL	10 mL Pharmacy Bulk Package Vial	25
0517-8005-25	5 mg/mL	5 mL Pharmacy Bulk Package Vial	25

1. I use an automated compounding device for parenteral nutrition (PN) preparations. Are there differences in the Specific Gravity, Osmolarity, and any other intrinsic values that I need to know to program into my compounding device?

For the FDA approved Zinc Sulfate Injection, the following values apply:

	1 mg/mL	3 mg/mL	5 mg/mL
Specific gravity	1.003 g/mL	1.008 g/mL	1.014 g/mL
Osmolarity	33 mOsmol/L	96.5 mOsmol/L	157.2 mOsmol/L
pH range	2 to 4	2 to 4	2 to 4

2. How should Zinc Sulfate be administered?

Zinc Sulfate Injection is for admixing use only. It is not for direct intravenous infusion. Prior to administration, Zinc Sulfate Injection must be transferred to a separate parenteral nutrition container, diluted, and used as an admixture in parenteral nutrition solutions.

3. What is the difference between a Single Dose Vial (SDV) and a Pharmacy Bulk Package (PBP) vial?

- A Single Dose Vial is intended for single use
- A Pharmacy Bulk Package vial is a sterile preparation that contains many single doses

4. How often can the PBP vial be entered?

Penetrate the vial closure one time only, with a suitable sterile transfer device, or a dispensing set that allows measured dispensing of the contents.

5. What is the stability of the final product that is prepared from a PBP?

- Use Zinc Sulfate Injection for admixing promptly, once the sterile transfer set has been inserted into the Pharmacy Bulk Package vial, or not more than 4 hours at room temperature 20°C to 25°C (68°F to 77°F) after the vial closure has been penetrated. Discard any remaining drug
- Use PN solution containing Zinc Sulfate Injection promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a period of time no longer than 9 days. After removal from refrigeration, use promptly and complete the infusion within 24 hours. Discard any remaining admixture
- Protect the admixed PN solution from light

6. Do any of the products contain preservatives?

No. All of our Zinc Sulfate formulations are preservative-free.

7. Are all products latex-free?

Yes. None of the vial closures are made with natural rubber latex.

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

E pv@americanregent.com; **F** 1.610.650.0170;
P 1.800.734.9236

ADEs may also be reported to the FDA at
1.800.FDA.1088
or to www.fda.gov/medwatch

Product Quality Complaints:
P 888.354.4859; **E** pqc@americanregent.com

Drug Information:
1.888.354.4855
(9:00 am – 5:00 pm Eastern Time, Monday – Friday)

For drug information outside of normal business hours, assistance is available at:
1-877-845-6371