

FREQUENTLY ASKED QUESTIONS

PACK NDC#	STRENGTH	SUPPLIED AS	SHELF PACK
0517-6101-25	1 mg/mL	10 mg/10 mL Pharmacy Bulk Package Vial	25
0517-6103-25	3 mg/mL	30 mg/10 mL Pharmacy Bulk Package Vial	25
0517-8005-25	5 mg/mL	25 mg/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:

- Osmolarity for 1 mg/mL product = 33 mOsmol/L
- Osmolarity for 3 mg/mL product = 96.5 mOsmol/L
- Osmolarity for 5 mg/mL product = 157.2 mOsmol/L
- Specific gravity for 1 mg/mL product = 1.003 g/mL
- Specific gravity for 3 mg/mL product = 1.008 g/mL
- Specific gravity for 5 mg/mL product = 1.014 g/mL
- pH range is 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 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) (25°C/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 brief period of time, no longer than 24 hours. After removal from refrigeration, use promptly and complete the infusion within 24 hours. Discard any remaining admixture.
- Protect the PN solution from light during storage.

6. Does the new product contain any preservatives?

No. The product is preservative-free.

7. Is the new product latex-free?

Yes. The vial closure is **not** made with natural rubber latex.

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

Product Quality Complaints:

Phone: 888-354-4859; **Email:** pqc@americanregent.com

Drug Information:

1-888-354-4855

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For urgent drug information outside of normal business hours, assistance is available at:

1-877-845-6371