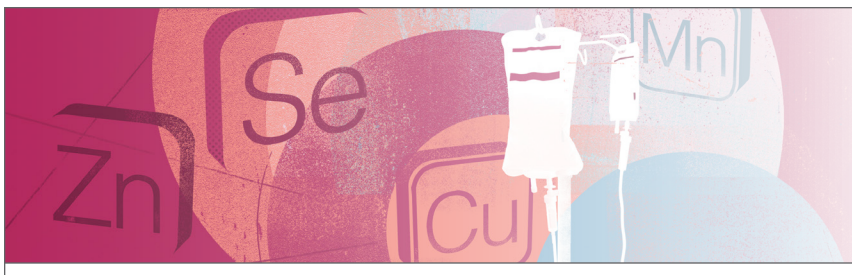

Tralement™

(trace elements injection 4*, USP)

*Each mL contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg.

FREQUENTLY ASKED QUESTIONS

Pack NDC#	Strength	Supplied As	Shelf Pack
0517-9305-25	Each mL provides zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg	1 mL Single Dose Vial	25

1. What is Tralement™ (trace elements injection 4*, USP)?

Tralement™ is the first and only FDA approved multi-trace element injection.[1] Tralement™ is indicated in adult and pediatric patients weighing at least 10 kg as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.[2]

2. What is the dosage form and strength of Tralement™?

Injection: 1 mL clear and colorless to slightly blue solution in a single-dose vial.[2]

*Each mL contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg.[2]

3. What is a single-dose vial?

A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case, procedure, or injection.[3]

4. What is the stability and storage of Tralement™?

- Single-dose vial. Discard unused portion.[2]
- Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F).[2]
- Use parenteral nutrition solutions containing Tralement™ 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 no longer than 9 days. After removal from refrigeration, use promptly and complete the infusion within 24 hours. Discard any remaining admixture.[2]
- Protect the parenteral nutrition solution from light.[2]

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

- Osmolarity: 114 mOsmol/L
- Specific Gravity: 1.009 (g/mL)
- pH range: 1.5 – 3.5

6. How is Tralement™ administered?

Tralement™ is not for direct intravenous infusion. Prior to administration, Tralement™ must be transferred to a separate parenteral nutrition container, diluted and used as an admixture in a parenteral nutrition solution.[2]

7. Does Tralement™ contain any preservatives?

No. The product is preservative-free.

8. Is Tralement™ latex-free?

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

9. What is the aluminum content of Tralement™?

Tralement™ contains no more than 6,000 mcg/L of aluminum.

10. Why did American Regent change its multi-trace element product formulation?

American Regent changed its formulation to align with ASPEN's pediatric and adult dosing recommendations for multi-trace elements.[4] In addition, to address the FDA's mandatory safety initiative to remove unapproved drugs from the market and ensure a consistent and reliable product supply, American Regent converted all adult Multitrace® products to a new single-dose product.[5]

11. Will a Tralement™ product that is indicated for patients under 10 kg be available in the future?

American Regent plans to launch a Neonatal Tralement™ product in the future.

12. Will American Regent introduce any additional Tralement™ products?

Other product presentations are under consideration.

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=209376#121. Accessed August 4, 2020.
2. Tralement™ (trace elements injection 4*) [package insert]. Shirley, NY: American Regent, Inc. 2020.
3. Center for Disease Control and Prevention Website: https://www.cdc.gov/injectionsafety/providers/provider_faqs_singlevials.html. Accessed on 6/30/2020
4. 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 July 20, 2020.
5. U.S. Food & Drug Administration: https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs. Accessed July 20, 2020.

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
(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

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Patents pending. PP-TR-US-0019 9/2020