FREQUENTLY ASKED QUESTIONS

Pack NDC#  | Strength | Supplied As  | Shelf Pack
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0517-8305-25 | Each mL provides: zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg | 1 mL | Single-dose vial

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

Tralement™ is the first and only FDA approved multi-trace element injection. 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. What is the dosage form and strength of Tralement™?

Injection: 1 mL clear and colorless to slightly blue solution in a single-dose vial, not for direct intravenous infusion. Each mL contains: zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg.

3. What is a single-dose vial?

A single-dose or single-use vial is a small unit of medication contained in a vial which is not intended for use in a single patient for a single case, procedure, or injection.

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

• Single-dose vial. Discard unused portion.
• Store at 2°C to 8°C (36°F to 46°F)
• Does not need refrigeration after opening.
• Protect the parenteral nutrition solution from light.

5. How is Tralement™ administered?

Tralement™ is indicated for use in a single patient for a single case, procedure, or injection. 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.

6. Does Tralement™ contain any preservatives?

No. The product is preservative-free.

7. What is the aluminum content of Tralement™?

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

8. Why did American Regent change its Multitrace product formulation?

American Regent changed its formulation to align with ASPEN’s pediatric and adult dosing recommendations for multi-trace elements. 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.

9. Why is manganese in the Tralement™ formulation?

Tralement™ provides 55 mcg of manganese in each mL, which is aligned with the 2012 A.S.P.E.N. Position Paper: “Recommendations for Changes in Commercially Available Parenteral Multivitamin and Multi–Trace Element Products,” which recommends that manganese in multi-trace element products be decreased to a maximum of 55 mcg per day. Do not supplement Tralement™ with additional manganese.

10. Why isn’t chromium included in this formulation?

During product selection and development, we assessed the literature and the current contents of current parenteral nutrition solutions. Tralement™ provides 55 mcg of manganese in each mL, which is aligned with the 2012 A.S.P.E.N. Position Paper: “Recommendations for Changes in Commercially Available Parenteral Multivitamin and Multi–Trace Element Products,” which recommends that manganese in multi-trace element products be decreased to a maximum of 55 mcg per day. Do not supplement Tralement™ with additional manganese.

11. What is the aluminum content of Tralement™?

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.

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

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16. Why isn’t chromium included in this formulation?

During product selection and development, we assessed the literature and the current contents of current parenteral nutrition solutions. Chromium is present in most parenteral solutions at the recommended daily dosage, and therefore, it is not a necessary trace element additive in Tralement™. The decision not to include chromium as an ingredient is aligned with the 2015 publication entitled, “A Call to Action to Bring Safer Parenteral Micronutrient Products to the US Market.”

17. 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.

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

Other product presentations are under consideration.

References
7. Hare DG, Smith NJ, and Galloway JW: “A Call to Action to Bring Safer Parenteral Micronutrient Products to the US Market: How is Tralement™ administered? 

You are encouraged to report Adverse Drug Events (ADEs) to American Regent:
Email: ADE@americanregent.com; Phone: 1-800-734-9236; Fax: 1-610-650-0170.

You may also be reported to the FDA at 1-800-FDA-1088 or to www.fda.gov/medwatch.

For urgent drug information outside of normal business hours, assistance is available at: 1-877-845-1706.

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