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, not for direct intravenous infusion.[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).[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] For complete dosing information, please refer to the Full Prescribing Information.

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 Multitrace® product formulation?

American Regent changed its formulation to align with ASPEN's pediatric and adult dosing recommendations for multi-trace elements.[4]

11. Why is manganese in the Tralement® 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.[6] Do not supplement Tralement® with additional manganese.

12. Why isn't chromium included in this formulation?

During product selection and development, we assessed the literature and the current contents of 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."[7]

13. 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.

14. 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 February 23, 2021.
2. Tralement® (trace elements injection 4*) [package insert]. Shirley, NY: American Regent, Inc. 7/2020.
3. Center for Disease Control and Prevention Website: https://www.cdc.gov/injectionsafety/providers/provider_faqs_singlevials.html. Accessed February 23, 2021.
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 February 23, 2021.
5. U.S. Food & Drug Administration: https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs. Accessed February 23, 2021.
6. Vanek et al. A.S.P.E.N. Position Paper: Recommendations for Changes in Commercially Available Parenteral Multivitamin and Multi-Trace Element Products. *Nutr Clin Pract.* Aug. 2012; 27 (4): 440-491.
7. Vanek et al. A Call to Action to Bring Safer Parenteral Micronutrient Products to the US Market. *Nutr Clin Pract.* Aug. 2015; 30 (4): 559-569.

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