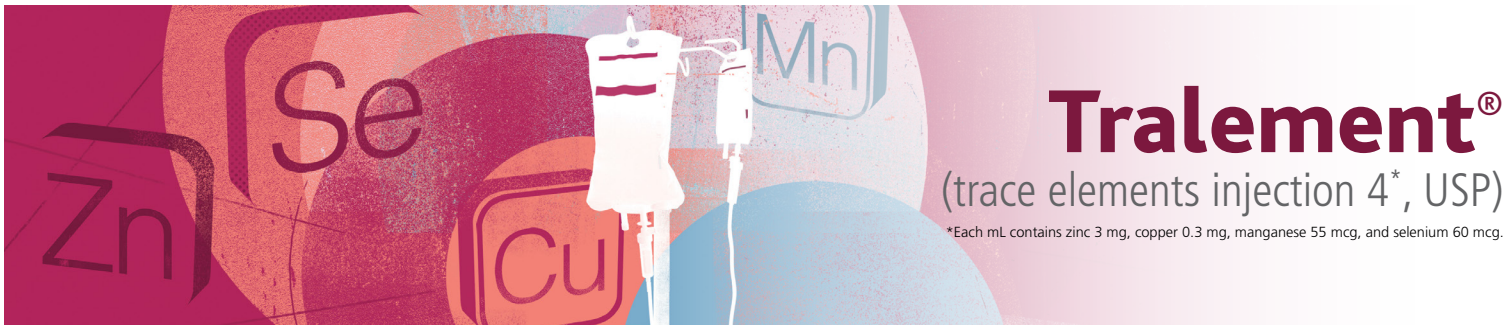

Tralement®

(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 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 (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.[2]

2. How is Tralement supplied?

Tralement is available in a 1 mL single-dose vial for *admixture use* only.

3. What is a single-dose vial?

A single-dose or single-use vial 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 PN 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 PN solution from light.[2]

5. I use an automated compounding device for 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 for *admixture use* only. It is *not for direct intravenous infusion*. Prior to administration, Tralement *must be transferred to a separate PN container*, diluted and used as an admixture in a PN solution for intravenous infusion.[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?

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.[2]

10. Why did the manganese content decrease in the Tralement formulation?

During product selection and development, we assessed the literature and the current contents of current parenteral nutrition (PN) 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.[4] Do not supplement Tralement with additional manganese.

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

During product selection and development, we assessed the literature and the current contents of PN 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."[5]

Tralement®

(trace elements injection 4*, USP)

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

For intravenous use

INDICATIONS AND USAGE

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.

IMPORTANT SAFETY INFORMATION

Important Administration Information

Tralement is supplied as a single-dose vial for *admixture use* only. It 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 parenteral nutrition solution.

Overview of Dosing

- Prior to administration of parenteral nutrition solution containing Tralement, correct severe fluid, electrolyte, and acid-base disorders.
- The dosage of the final parenteral nutrition solution containing Tralement must be based on the concentrations of all components in the solution, the patient's clinical condition, nutritional requirements, and the contribution of oral or enteral intake.

Tralement is recommended only for patients who require supplementation with all four of the individual trace elements (i.e., zinc, copper, manganese and selenium).

See Full Prescribing Information on preparation, administration and dosing.

CONTRAINDICATIONS

Tralement is contraindicated in patients with hypersensitivity to zinc or copper.

WARNINGS AND PRECAUTIONS

- Pulmonary Embolism due to Pulmonary Vascular Precipitates: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation.
- Vein Damage and Thrombosis: Solutions with osmolarity of 900 mOsmol/L or more must be infused through a central catheter. The primary complication of peripheral access is venous thrombophlebitis.
- Neurologic Toxicity with Manganese: Monitor patients receiving long-term parenteral nutrition solutions containing Tralement for neurologic signs and symptoms and routinely monitor whole blood manganese concentrations and liver function tests. Discontinue Tralement and consider brain magnetic resonance imaging (MRI) if toxicity suspected.
- Hepatic Accumulation of Copper and Manganese: Assess for development of hepatic or biliary dysfunction. Monitor concentrations of copper and manganese in patients with cholestasis, biliary dysfunction or cirrhosis receiving Tralement long-term.
- Aluminum Toxicity: Tralement contains aluminum that may be toxic. Increased risk in patients with renal impairment, including preterm infants.
- Monitoring and Laboratory Tests: Monitor blood zinc, copper, manganese, and selenium concentrations, fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters.
- Hypersensitivity Reactions with Zinc and Copper: If reactions occur, discontinue Tralement and initiate appropriate medical treatment.

ADVERSE REACTIONS

The following adverse reactions were identified in clinical studies or post-marketing reports. Given that some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Adverse reactions with other components of parenteral nutrition solutions:

- Pulmonary embolism due to pulmonary vascular precipitates
- Vein damage and thrombosis
- Aluminum toxicity

Adverse reactions with the use of trace elements administered parenterally or by other routes of administration:

- Neurologic toxicity with manganese
- Hepatic accumulation of copper and manganese
- Hypersensitivity reactions with zinc and copper

USE IN SPECIFIC POPULATIONS

Pregnancy - Risk Summary - Deficiency of trace elements may result in adverse pregnancy and fetal outcomes.

Lactation - Risk Summary - Zinc, copper, manganese, and selenium are present in human milk. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Tralement and any potential adverse effects on the breastfed infant from Tralement or from the underlying maternal condition.

Pediatric Use - Refer to Full Prescribing Information for dosing. Do not supplement Tralement with additional manganese. Tralement is not approved for use in pediatric patients weighing less than 10 kg.

Hepatic Impairment - Hepatic accumulation of copper and manganese have been reported with long-term administration in parenteral nutrition. For patients with cholestasis, biliary dysfunction, or cirrhosis, monitor hepatic and biliary function during long-term administration of Tralement.

OVERDOSAGE - There are reports on overdosage in the literature for the individual trace elements. Management of overdosage is supportive care based on presenting signs and symptoms.

For additional safety information, please see the Full Prescribing Information.

You are encouraged to report Adverse Drug Events to American Regent, Inc. at 1-800-734-9236, or to the FDA by visiting www.fda.gov/medwatch or by calling 1-800-FDA-1088.

REF-1535 v6.0 2/2021

References

1. Orange book: approved drug products with therapeutic equivalence evaluations: product details for NDA 209376. US Food & Drug Administration. Accessed November 3, 2022. Tralement®: https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=209376
2. Tralement (trace elements injection 4*). Package insert. American Regent, Inc.; 2020.
3. Questions about Single-dose/Single-use Vials. Center for Disease Control and Prevention. Accessed November 3, 2022. https://www.cdc.gov/injectionsafety/providers/provider_faqs_singlevials.html
4. Vanek VW, Borum P, Buchman A, 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*. 2012;27(4):440-491.
5. Vanek et al. A Call to Action to Bring Safer Parenteral Micronutrient Products to the US Market. *Nutr Clin Pract*. 2015;30(4):559-569.

You are encouraged to report adverse drug events (ADEs) to American Regent:
T 1.800.734.9236; **E** pv@americanregent.com; **F** 1.610.650.0170

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

Medical information:
T 1.888.354.4855 (9:00 am–5:00 pm Eastern Time, Monday–Friday)
W www.americanregent.com/medical-affairs

For medical information outside of normal business hours
that cannot wait until the next business day, please call 1.877.845.6371

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