
# 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?**
   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?**
   - Tralement is supplied in a single-use vial. Any unused portion should be discarded.[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 the PN container* 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 aligned Tralement with the 2012 ASPEN 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 provides zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg

**For intravenous use**

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

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

### WARNINGS AND PRECAUTIONS

Pulmonary Embolism due to Pulmonary Vascular Precipitates: Pulmonary vascular precipitates causing pulmonary vascular emboli and pulmonary distress have been reported in patients receiving parenteral nutrition. If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation.

Vein Damage and Thrombosis: Tralement must be prepared and used as an admixture in parenteral nutrition solution. It is not for direct intravenous infusion. In addition, consider the osmolarity of the final parenteral nutrition solution in determining peripheral versus central administration. 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: If a patient develops signs or symptoms of hepatic or biliary dysfunction during the use of Tralement, obtain serum concentrations of copper and ceruloplasmin as well as manganese whole blood concentrations. Consider using individual trace element products in patients with hepatic and/or biliary dysfunction.

Aluminum Toxicity: Tralement contains aluminum that may be toxic. Increased risk in patients with renal impairment. Preterm infants, including preterm neonates, are particularly at risk.

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 hypersensitivity 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 because the product does not provide an adequate dosage of zinc, copper, or selenium to meet the needs of this subpopulation and exceeds the recommended dosage of manganese.

**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.

## 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.

**For additional safety information, please see 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.**

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**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)
www.americanregent.com/medical-affairs

**REFERENCES:**


**1**. Orange book: Approved Drug Products with Therapeutic Equivalence Evaluations: Product Details for NDA 209376. US Food & Drug Administration. Accessed August 25, 2025. 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.

**3.** Questions about Single-dose/Single-use Vials. Center for Disease Control and Prevention. Accessed August 25, 2025. https://www.cdc.gov/injection-safety/hcp/clinical-safety/?CDC_AAref_Val=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.



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