



# Tralement<sup>®</sup>

(trace elements injection 4\*, USP)

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

## Tralement is the only FDA-approved multi-trace element injection for parenteral nutrition indicated for use in patients weighing at least 10 kg<sup>1</sup>

Tralement (trace elements injection 4\*, USP) 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.<sup>2</sup>

### Aligns with current treatment guidelines

Tralement has been specifically developed to align with the ASPEN Dosing Recommendations for trace element supplementation. The concentration of each element in Tralement has been formulated to meet the needs of a broad range of pediatric and adult patients.<sup>2,3</sup>

Tralement is contraindicated in patients with hypersensitivity to zinc or copper. **Please refer to the following pages for the Tralement Important Safety Information.**

### Dosing: Added to parenteral nutrition

A 1 mL dose of Tralement per day for adults and pediatric

patients weighing at least 50 kg simplifies treatment planning and preparation for healthcare workers, may save time, and may reduce the likelihood of errors.<sup>2,4</sup> Weight-dependent dosing is provided for pediatric patients between 10 kg to 49 kg.<sup>2</sup> Tralement is not recommended for patients who may require a lower dosage of 1 or more of the individual trace elements.

### Proven stability

Stability studies support that Tralement can be safely stored for up to 9 days when added to the parenteral nutrition admixture and refrigerated.<sup>2</sup>

### Consistent supply

Tralement is proudly manufactured in America. American Regent<sup>®</sup> is committed to providing a consistent supply to help ensure that your patient care needs are met.

Tralement aligns with the daily recommendations for parenteral trace elements set forth by ASPEN.<sup>2,3</sup>

## ADULT TRACE ELEMENT DOSING

Trace element	ASPEN adult standard daily requirement	Tralement per 1 mL
Zinc	3-5 mg	3 mg
Copper	0.3-0.5 mg	0.3 mg
Manganese	55 mcg	55 mcg
Selenium	60-100 mcg	60 mcg
Chromium	≤10 mcg	0 mcg



## TRALEMENT® DOSING RECOMMENDATIONS FOR PEDIATRIC PATIENTS WEIGHING 10 kg TO 49 kg<sup>2</sup>

The recommended dosage of Tralement based on body weight is 0.2–0.8 mL per day added to parenteral nutrition. Tralement does not provide the recommended daily dosage of zinc (in heavier patients in some weight bands), copper, or selenium. Additional supplementation may be needed for these patients.<sup>2</sup>

Patient Population	Body Weight	Tralement Dosage	Zinc	Copper	Manganese	Selenium
Pediatric	10 kg to 19 kg	0.2 mL	600 mcg	60 mcg	11 mcg	12 mcg
Pediatric	20 kg to 29 kg	0.4 mL	1,200 mcg	120 mcg	22 mcg	24 mcg
Pediatric	30 kg to 39 kg	0.6 mL	1,800 mcg	180 mcg	33 mcg	36 mcg
Pediatric	40 kg to 49 kg	0.8 mL	2,400 mcg	240 mcg	44 mcg	48 mcg

See [Full Prescribing Information](#) for complete and Important Dosage and Administration information.

Refer to the table below for specifications on Tralement (trace elements injection 4\*, USP) by American Regent®. For additional information, visit [www.americanregent.com](http://www.americanregent.com).

## AMERICAN REGENT TRACE ELEMENT PRODUCT SPECIFICATIONS

Product	<b>Tralement</b> Pediatric and adult patients weighing at least 10 kg
Approval status	<b>FDA-approved<sup>1</sup></b>
Pack NDC	0517-9305-25 <sup>2</sup>
Trace elements per mL	<ul style="list-style-type: none"> <li>• Zinc 3 mg</li> <li>• Copper 0.3 mg</li> <li>• Manganese 55 mcg</li> <li>• Selenium 60 mcg</li> </ul>
Vial type	Single-dose vial
Fill volume	1 mL
Preservative	Preservative-free
Specific gravity	1.009 (g/mL)
Cap color	Garnet
Aluminum content	No more than 6,000 mcg/L of aluminum
Pack size	25
Storage	Store at 20°C to 25°C (68°F to 77°F)
Trace element stability in TPN	Up to 9 days when added to the PN admixture and refrigerated



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

NDC=National Drug Code; PN=parenteral nutrition; TPN=total parenteral nutrition.

# Tralement<sup>®</sup>

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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

### 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, including 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.

### 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).

**For additional safety information, please see the [Full Prescribing Information](#).**

**You are encouraged to report Adverse Drug Events to American Regent, Inc.<sup>®</sup> at 1-800-734-9236, or to the FDA by visiting [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or by calling 1-800-FDA-1088.**

**You are encouraged to report adverse drug events (ADEs) to American Regent®:**

**T** 1.800.734.9236; **E** [pv@americanregent.com](mailto: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](http://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](http://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

**References:**

1. Orange book: approved drug products with therapeutic equivalence evaluations: product details for NDA 209376. US Food & Drug Administration. Accessed April 18, 2024. Tralement®: [https://www.accessdata.fda.gov/scripts/cder/ob/results\\_product.cfm?Appl\\_Type=N&Appl\\_No=209376](https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=209376)
2. Tralement (trace elements injection 4\*, USP). Package insert. American Regent, Inc.
3. American Society for Parenteral and Enteral Nutrition. Appropriate dosing for parenteral nutrition: ASPEN Recommendations. November 17, 2020. Accessed April 18, 2024. [http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines\\_and\\_Clinical\\_Resources/PN%20Dosing%201-Sheet-FINAL.pdf](http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-FINAL.pdf)
4. Vanek VW, Borum P, Buchman A, et al; Novel Nutrient Task Force; Parenteral Vitamin and Trace Element Working Group; American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.). A call to action to bring safer parenteral micronutrient products to the U.S. market. *Nutr Clin Pract*. 2015;30(4):559-569.



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