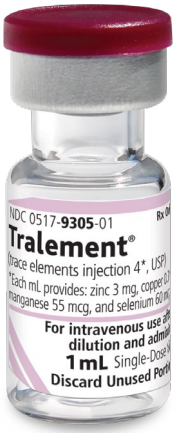
Tralement®

(trace elements injection 4*, USP)

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

Actor portrayal

Adult & pediatric dosing and administration guide



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The first FDA-approved multi-trace element injection for parenteral nutrition.[1]

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.[2]

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

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.[2,3]

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Dosing: Added to parenteral nutrition

The recommended dosage of Tralement® is 1 mL per day added to parenteral nutrition.[2] Weight-dependent dosing is provided for pediatric patients between 10 kg to 49 kg.[2] 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.[2]

Consistent supply

Tralement is proudly manufactured in the US with active pharmaceutical ingredients sourced in the US.

Dosing for adults and pediatric patients weighing at least 50 kg

For adults and pediatric patients weighing at least 50 kg, the recommended dose is 1 mL per day added to parenteral nutrition.[2]

Pediatric dosing

For pediatric patients weighing 10 kg to 49 kg, the recommended dosage of Tralement is based on body weight and ranges from 0.2 to 0.8 mL per day.[2] (Please refer to Table 1)

SELECT IMPORTANT SAFETY INFORMATION

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.

Table 1. Recommended weight-based daily dosage of Tralement®

Patient population	Body weight	Tralement Dosage (mL)	Amount of trace elements provided by the corresponding Tralement volume			
			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	1200 mcg	120 mcg	22 mcg	24 mcg
Pediatric	30 kg to 39 kg	0.6 mL	1800 mcg	180 mcg	33 mcg	36 mcg
Pediatric	40 kg to 49 kg	0.8 mL	2400 mcg	240 mcg	44 mcg	48 mcg
Adult and Pediatric	At least 50 kg	1 mL	3 mg	0.3 mg	55 mcg	60 mcg

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- 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.

Supplementation with individual trace elements

For pediatric patients weighing 10 kg to 49 kg, additional zinc (in heavier patients in some weight bands), copper and selenium may be required to meet the recommended daily dose (shown below). To determine the additional amount of supplementation, compare the recommended daily dosage based on the body weight of the patient to the amount of each trace element provided by Tralement® and other dietary resources.[2]

- Zinc: 50 mcg/kg/day (up to 3,000 mcg/day)
- Copper: 20 mcg/kg/day (up to 300 mcg/day)
- Selenium: 2 mcg/kg/day (up to 60 mcg/day)

Do not supplement Tralement with additional manganese.

Additional details for dosage and administration

- Tralement, supplied as a 1 mL single-dose vial, is *not for direct intravenous infusion* and is used as an additive in parenteral nutrition admixtures.
- 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 not approved for pediatric patients weighing less than 10 kg because the product does not provide an adequate dosage of zinc, copper, or selenium, and exceeds the recommended dosage of manganese.
- Prior to administration of parenteral nutrition solution containing Tralement, correct severe fluid, electrolyte, and acid-base disorders.
- Monitor fluid and electrolyte status during treatment use of Tralement and adjust the parenteral nutrition solution as needed.
- Monitor trace element concentrations in blood during long-term administration. of parenteral nutrition. The dosage of the final Parenteral Nutrition solution containing Tralement must be based upon all components of the solution, the patient's clinical condition, and the contribution of all oral or enteral intake.

Table 2: Intrinsic values for automated compounding devices for parenteral nutrition (PN) preparations

Intrinsic value	Tralement
Osmolarity	114 mOsmol/L
Specific gravity	1.009 (g/mL)
pH range	1.5-3.5

For complete information, including dosing and administration, please see the Full Prescribing Information.

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- 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.

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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. 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 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 7/2020

REFERENCES:

1. Orange book: approved drug products with therapeutic equivalence evaluations: product details for NDA 209376. US Food & Drug Administration. Accessed January 30, 2024. Tralement®: 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 January 5, 2024. http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-FINAL.pdf

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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

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

For additional information on Tralement, please visit www.artraceelements.com

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AMERICAN REGENT®

Reliable. Responsive. Respected.