

Tralement[®]

(trace elements injection 4*, USP)

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

PRODUCT INFORMATION BULLETIN

Tralement[®] is the only FDA-approved multi-trace element injection for parenteral nutrition indicated for use in patients weighing at least 10 kg¹

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

planning and preparation for healthcare workers, may save time, and may reduce the likelihood of errors.^{2,4} 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.

- 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}

- 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

- 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

- Consistent supply

Tralement[®] is proudly manufactured in America. American Regent 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.^{2,3}

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



PEDIATRIC TRACE ELEMENT DOSING

Trace element	ASPEN dosing recommendations ³		Tralement® (trace elements injection 4*, USP)
	Children 10-40 kg	Adolescents greater than 40 kg	Pediatric weight-based dosage for Tralement® for patients weighing 10-49 kg ²
Zinc	50 mcg/kg (max 5,000 mcg/day)	2-5 mg	50 mcg/kg/day (up to 3,000 mcg/day)
Copper	20 mcg/kg (max 500 mcg/day)	200-500 mcg	20 mcg/kg/day (up to 300 mcg/day)
Manganese	1 mcg/kg (max 55 mcg/day)	40-100 mcg	1 mcg/kg/day (up to 55 mcg/day)
Selenium	2 mcg/kg (max 100 mcg/day)	40-60 mcg	2 mcg/kg/day (up to 60 mcg/day)
Chromium	0.2 mcg/kg (max 5 mcg/day)	5-15 mcg	0 mcg

Refer to the table below for specifications on Tralement® (trace elements injection 4*, USP) and Multrys™ (trace elements injection 4*, USP) by American Regent. For additional information, visit www.americanregent.com.

AMERICAN REGENT TRACE ELEMENT PRODUCT SPECIFICATIONS

Product	Tralement® Pediatric and adult patients weighing at least 10 kg	Multrys™ Neonatal and pediatric patients weighing less than 10 kg
	Approval status	FDA-approved ¹
Pack NDC	0517-9305-25 ²	0517-9302-25 ⁶
Trace elements per mL	<ul style="list-style-type: none"> • Zinc 3 mg • Copper 0.3 mg • Manganese 55 mcg • Selenium 60 mcg 	<ul style="list-style-type: none"> • Zinc 1,000 mcg • Copper 60 mcg • Manganese 3 mcg • Selenium 6 mcg
Vial type	Single-dose vial	Single-dose vial
Fill volume	1 mL	1 mL
Preservative	Preservative-free	Preservative-free
Specific gravity	1.009 (g/mL)	1.004 (g/mL)
Cap color	Garnet	Aqua
Aluminum content	No more than 6,000 mcg/L of aluminum	No more than 1,500 mcg/L of aluminum
Pack size	25	25
Storage	Store at 20°C to 25°C (68°F to 77°F)	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	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.
Each mL of Multrys™ contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg.

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

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.

Multrys™

(trace elements injection 4*, USP)

*Each mL contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg.

For intravenous use

INDICATIONS AND USAGE

Multrys™ is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated in neonatal and pediatric patients weighing less than 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

DOSAGE AND ADMINISTRATION

Important Administration Information

Multrys is supplied as a single-dose vial. Prior to administration, Multrys *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 Multrys, correct severe fluid, electrolyte and acid-base disorders. It is recommended only for patients who require supplementation with all four of the individual trace elements (zinc, copper, manganese and selenium). Multrys is not recommended for patients who may require a lower dosage of one or more of the individual trace elements. Avoid additional manganese supplementation with Multrys use.

CONTRAINDICATIONS

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 parenteral nutrition infusion and initiate a medical evaluation.

Vein Damage and Thrombosis: Solution with an osmolality of 900 mOsmol/L or greater must be infused through a central catheter.

Neurologic Toxicity with Manganese: Monitor for clinical signs and symptoms of neurotoxicity, whole blood manganese concentrations, and liver function tests. Discontinue Multrys and

consider brain magnetic resonance imaging (MRI) if toxicity is suspected. Monitor patients for cholestasis or other biliary liver disease.

Hepatic Accumulation of Copper and Manganese: Assess for development of hepatic accumulation. Monitor concentrations of copper and manganese in patients with cholestasis or cirrhosis.

Aluminum Toxicity: Multrys contains aluminum that may be toxic. Patients with renal impairment and preterm infants, including preterm neonates, are particularly at risk.

Monitoring and Laboratory Tests: Monitor blood zinc, copper and selenium serum concentrations, whole blood manganese concentration, fluid and electrolyte status, serum osmolality, blood glucose, liver and kidney function, blood count, and coagulation parameters.

Hypersensitivity Reactions with Zinc and Copper:

If hypersensitivity reactions occur, discontinue and initiate appropriate medical treatment.

ADVERSE REACTIONS

The following adverse reactions were identified in clinical studies or post-marketing reports:

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

OVERDOSAGE

There are reports on overdosage in the literature for the individual trace elements.

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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References:

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2. Tralement® (trace elements injection 4*, USP) [package insert]. Shirley, NY: American Regent, Inc. 7/2020.
3. American Society for Parenteral and Enteral Nutrition. Appropriate dosing for parenteral nutrition: ASPEN Recommendations. November 17, 2020. Accessed May 16, 2022. 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.
5. Orange book: approved drug products with therapeutic equivalence evaluations: product details for NDA 209376. US Food & Drug Administration. Accessed May 16, 2022. Multrys™: https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=209376
6. Multrys™ (trace elements injection 4*, USP) [package insert]. Shirley, NY: American Regent, Inc. 6/2021.

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



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