

# Multrys™

(trace elements injection 4\*, USP)

Formulated to Meet Today's Guidelines†

\*Each mL contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg.  
 †Formulated to more closely align with the 2019 ASPEN Dosing Recommendations.



## Introducing Multrys™:

# A multiple trace elements injection for neonatal and pediatric patients weighing under 10 kg

**Multrys** (trace elements injection 4\*, USP) is a combination of trace elements (zinc sulfate, cupric sulfate, manganese sulfate, and selenious acid) indicated for neonatal and pediatric patients weighing less than 10 kg.<sup>1</sup>

The concentration of each element in **Multrys** has been formulated to meet the needs of **neonatal and pediatric patients weighing less than 10 kg**.<sup>1</sup>

The concentration of each element in **Tralement**® (trace elements injection 4\*, USP) is formulated to meet the needs of **adult and pediatric patients weighing at least 10 kg**.<sup>2</sup>

Both products are used as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.<sup>1,2</sup>

\*Each mL of **Multrys** contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg.  
 Each mL of **Tralement** contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg.

- **Aligns with current treatment guidelines**

**Multrys** has been specifically developed to more closely align with the ASPEN (American Society for Parenteral and Enteral Nutrition) Dosing Recommendations for trace elements supplementation than previously marketed products<sup>3</sup>

- **Proven stability**

Stability studies support that **Multrys** can be safely stored for up to 9 days when added to the parenteral nutrition admixture and refrigerated<sup>1</sup>

- **Consistent supply**

**Multrys** is proudly manufactured in the US with active pharmaceutical ingredients and components sourced in the US. Our supply chain is short and less complicated. As a result, American Regent is uniquely positioned to provide you with supply consistency to help ensure critical medications reach patients faster

Please see the table below for product specifications. For additional information, please visit [www.americanregent.com](http://www.americanregent.com)

## PRODUCT SPECIFICATIONS

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

ASPEN=American Society for Parenteral and Enteral Nutrition; NDC=National Drug Code; PN=parenteral nutrition; TPN=total parenteral nutrition.

**Multrys™ (trace elements injection 4\*, USP) and Tralement® (trace elements injection 4\*, USP) more closely align with the daily recommendations for parenteral trace elements set forth by ASPEN.<sup>3</sup>**

\*Each mL of **Multrys** contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg.  
Each mL of **Tralement** contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg.

## Multrys™

(trace elements injection 4\*, USP)

### DAILY PN RECOMMENDATIONS COMPARISON—NEONATAL AND PEDIATRIC PATIENTS WEIGHING LESS THAN 10 KG

Trace element	ASPEN: PN trace elements daily dosing <sup>3</sup>		American Regent daily requirement for trace elements supplementation by patient weight <sup>1</sup>		
	Preterm neonates	Term neonates 3 kg-10 kg	Less than 3 kg	3 kg-5 kg	5 kg-10 kg
Zinc	400 mcg/kg	250 mcg/kg	400 mcg/kg	250 mcg/kg	100 mcg/kg
Copper	20 mcg/kg	20 mcg/kg	20 mcg/kg	20 mcg/kg	20 mcg/kg
Manganese	1 mcg/kg	1 mcg/kg	1 mcg/kg	1 mcg/kg	1 mcg/kg
Selenium	2 mcg/kg	2 mcg/kg	2 mcg/kg	2 mcg/kg	2 mcg/kg
Chromium	0.05-0.3 mcg/kg	0.2 mcg/kg	0 mcg/kg	0 mcg/kg	0 mcg/kg



#### Multrys dosing: Added to parenteral nutrition<sup>1</sup>

**Pediatric patients weighing 0.4 kg to 0.59 kg:** The total recommended dosage of Multrys is 0.2 mL **every other day**. Daily supplementation of zinc, copper, and selenium will be needed to meet daily requirements. **Pediatric patients weighing 0.6 kg to less than 10 kg:** The recommended dosage of Multrys is 0.3 mL/kg/day rounded to the nearest 0.1 mL for up to a maximum of 1 mL per day. **Additional trace elements supplementation with Multrys:** To determine the additional amount of supplementation needed, compare the calculated daily recommended dosage based on the body weight of the patient to the amount of each trace element provided by Multrys and enteral nutrition sources. Multrys is not recommended for pediatric patients who may require a lower dosage of 1 or more of these individual trace elements. Avoid additional manganese supplementation with Multrys use. Accumulation of manganese in the brain can occur with long-term administration of higher than recommended dosage of 1 mcg/kg/day.

For complete information, including dosage and administration, please see the [Full Prescribing Information](#).

## Tralement®

(trace elements injection 4\*, USP)

### DAILY PN RECOMMENDATIONS COMPARISON—PEDIATRIC PATIENTS 10 KG TO 49 KG

Trace element	ASPEN daily dosing recommendations <sup>3</sup>		American Regent daily dosing recommendations <sup>2</sup>
	Children 10 kg-40 kg	Adolescents greater than 40 kg	Pediatric weight-based dosage for patients weighing 10 kg-49 kg <sup>2</sup>
Zinc	50 mcg/kg ( <i>max 5,000 mcg/day</i> )	2-5 mg	50 mcg/kg/day ( <i>up to 3,000 mcg/day</i> )
Copper	20 mcg/kg ( <i>max 500 mcg/day</i> )	200-500 mcg	20 mcg/kg/day ( <i>up to 300 mcg/day</i> )
Manganese	1 mcg/kg ( <i>max 55 mcg/day</i> )	40-100 mcg	1 mcg/kg/day ( <i>up to 55 mcg/day</i> )
Selenium	2 mcg/kg ( <i>max 100 mcg/day</i> )	40-60 mcg	2 mcg/kg/day ( <i>up to 60 mcg/day</i> )
Chromium	0.2 mcg/kg ( <i>max 5 mcg/day</i> )	5-15 mcg	0 mcg

The recommended dosage of Tralement based on body weight is 0.2 mL to 0.8 mL per day added to parenteral nutrition. For pediatric patients weighing 10 kg to 49 kg, additional zinc (in heavier patients in some weight bands), copper, and selenium may be needed to meet the recommended daily dosage of these trace elements.<sup>2</sup>

### DAILY PN RECOMMENDATIONS COMPARISON—ADULT

Trace element	ASPEN adult daily dosing recommendations <sup>3</sup>	American Regent daily dosing recommendations <sup>2</sup>
		Dosage for adults weighing at least 50 kg <sup>2</sup>
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: 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> Tralement is not recommended for patients who may require a lower dosage of 1 or more of the individual trace elements.<sup>2</sup> For complete information, including dosage and administration, please see the [Full Prescribing Information](#).

# 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 osmolarity 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 osmolarity, 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](http://www.fda.gov/medwatch) or by calling 1-800-FDA-1088.

REF-1826 6/2021

# 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 osmolality 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 osmolality, 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 [Full Prescribing Information](#).**

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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](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 business hours that cannot wait until the next business day, please call 1.877.845.6371

## REFERENCES:

1. Multrys (trace elements injection 4\*) [package insert]. Shirley, NY: American Regent, Inc. 6/2021.
2. Tralement (trace elements injection 4\*) [package insert]. Shirley, NY: American Regent, Inc. 10/2020.
3. American Society for Parenteral and Enteral Nutrition. Appropriate dosing for parenteral nutrition: ASPEN Recommendations. November 17, 2020. Accessed September 9, 2021. [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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