Multrys®

(trace elements injection 4*, USP)

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

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

Multrys 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.[1]

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

Multrys is used as a source of zinc, copper, manganese, and selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.[1]

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

• Aligns with current treatment guidelines

Multrys has been specifically developed to more closely align with the American Society for Parenteral and Enteral Nutrition Dosing Recommendations for trace elements supplementation.

• 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.[1]

• Consistent supply

Multrys is proudly manufactured in the US with active pharmaceutical ingredients and components sourced in the US. Our supply chain is short so, as a result, American Regent is positioned to provide you with supply consistency to help ensure critical medications reach you quickly.

Please refer to the table to the right for product details. See Important Safety Information on the next page, and visit www.americanregent.com for additional details on Multrys.

Product Information

Multrys
Neonatal and pediatric patients weighing less than 10 kg

Approval status	**FDA-approved**
Pack NDC	0517-9302-25
Trace elements per mL	• Zinc 1,000 mcg • Copper 60 mcg • Manganese 3 mcg • Selenium 6 mcg
Vial type	Single-dose vial
Fill volume	1 mL
Preservative	Preservative-free
Specific gravity	1.004 (g/mL)
Cap color	Aqua
Aluminum content	No more than 1,500 mcg/L of aluminum
Pack size	25
Storage	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

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

Multrys® (trace elements injection 4*, USP) more closely aligns with the daily recommendations for parenteral trace elements set forth by the American Society for Parenteral and Enteral Nutrition (ASPEN).[2]

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Daily parenteral nutrition (PN) recommendations comparison—neonatal and pediatric patients weighing less than 10 kg

Trace element	ASPEN: PN trace elements daily dosing[2]		Multrys label: Daily requirement of trace element supplementation for pediatric patients[1]		
	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[1]

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:** Multrys is recommended only for pediatric patients who require supplementation with all four of the individual trace elements (ie, zinc, copper, manganese, and selenium). 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.

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For intravenous use

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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 parenteral nutrition infusion and initiate a medical evaluation.

IMPORTANT SAFETY INFORMATION
(continued)

Vein Damage and Thrombosis: Multrys 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. Solution with an osmolarity of 900 mOsmol/L or greater must be infused through a central catheter. The infusion of hypertonic nutrient solution into a peripheral vein may result in vein irritation, vein damage, and/or thrombosis.

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: If a patient develops signs or symptoms of hepatobiliary disease during the use of Multrys, obtain serum concentrations of copper and ceruloplasmin as well as manganese whole blood concentrations; consider using individual trace element products in these patients.

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. 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
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 Multrys.

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
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.

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;
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. Multrys (trace elements injection 4*, USP). Package insert. American Regent, Inc.
2. American Society for Parenteral and Enteral Nutrition. Appropriate dosing for parenteral nutrition: ASPEN Recommendations. November 17, 2020.

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