FREQUENTLY ASKED QUESTIONS

Pack NDC#	Strength	Supplied as	Shelf pack
0517-9302-25	Each mL contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg	1 mL Single-dose vial	25

1. **What is Multrys?**
   Multrys is an FDA-approved multi-trace element injection indicated for use in neonatal and pediatric patients weighing less than 10 kg. It is used as a source of zinc, copper, manganese, and selenium for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.[1]

2. **How is Multrys supplied?**
   Multrys is available in a 1 mL single-dose vial for *admixture use only*.[1]

3. **What is a single-dose vial?**
   A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case, procedure, or injection.[2]

4. **What is the stability and storage of Multrys?**

- Multrys is supplied in a single-use vial. Any unused portion should be discarded[1]
- Store at 20°C to 25°C (68°F to 77°F).[1] See USP Controlled Room Temperature
- Use PN solutions containing Multrys promptly after mixing. Any storage of the admixture should be under refrigeration from 2°C to 8°C (36°F to 46°F) and limited to a period of no longer than 9 days. After removal from refrigeration, use promptly and complete the infusion within 24 hours. Discard any remaining admixture[1]
- Protect the PN solution from light[1]

5. **I use an automated compounding device for PN preparations. What are the Specific Gravity, Osmolarity, and any other intrinsic values that I need to know to program into my compounding device?**

Intrinsic Value	Multrys
Osmolarity	39 mOsmol/L
Specific Gravity	1.004 (g/mL)
pH Range	1.5–3.5

6. **How is Multrys administered?**
   Multrys is for admixture use only. Prior to administration, Multrys *must be transferred to the PN container*, and used as an admixture in PN solution for intravenous infusion. See **Full Prescribing Information** for complete dosing and administration information.[1]

7. **Does Multrys contain any preservatives?**
   No. Multrys is preservative-free.

8. **Is Multrys latex-free?**
   The vial closure *is not* made with natural rubber latex.

9. **What is the aluminum content of Multrys?**
   Multrys contains no more than 1,500 mcg/L of aluminum.

10. **Why did American Regent® launch Multrys?**
    American Regent launched Multrys to more closely align with the American Society for Parenteral and Enteral Nutrition (ASPEN) neonatal and pediatric dosing recommendations for trace element supplementation than products previously marketed by American Regent.[3]

11. **Why is manganese included in the Multrys formulation?**
    Manganese is included in the Multrys formulation to more closely align with the 2012 ASPEN position paper, "Recommendations for Changes in Commercially Available Parenteral Multivitamin and Multi-Trace Element Products."[4]

12. **Why isn't chromium included in these formulations?**
    During product selection and development, we assessed the literature and the current contents of parenteral nutrition solutions. Chromium is present in most parenteral solutions at the recommended daily dosage, and therefore, it is not a necessary trace element additive in Multrys. The decision not to include chromium as an ingredient is aligned with the 2015 ASPEN publication entitled, "A Call to Action to Bring Safer Parenteral Micronutrient Products to the US Market."[5]

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

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.

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.

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-1826 7/2024

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. Questions about single-dose/single-use vials. Centers for Disease Control and Prevention. Updated June 20, 2019. Accessed August 13, 2025. https://www.cdc.gov/injection-safety/hcp/clinical-safety/?CDC_AAref_Val=https://www.cdc.gov/injectionsafety/providers/provider_faqs_singlevials.html

3. Appropriate dosing for parenteral nutrition: ASPEN recommendations. American Society for Parenteral and Enteral Nutrition. Published November 17, 2020.

4. Vanek VW, Borum P, Buchman A, et al. A.S.P.E.N. Position Paper: Recommendations for Changes in Commercially Available Parenteral Multivitamin and Multi-Trace Element Products. *Nutr Clin Pract.* 2012;27(4):440-491.

5. Vanek VW, Borum P, Buchman A, et al. Call to Action to Bring Safer Parenteral Micronutrient Products to the US Market. *Nutr Clin Pract.* 2015;30(4):559-569.

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