FREQUENTLY ASKED QUESTIONS

Brand	Pack NDC#	Strength	Supplied as	Shelf pack
Multrys®	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 (trace elements injection 4*, USP)?**
   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.[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?**
   - Single-dose vial. Discard unused portion[1]
   - Store at 20°C to 25°C (68°F to 77°F).[1] See USP Controlled Room Temperature
   - Use parenteral nutrition 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 parenteral nutrition solution from light[1]

5. **I use an automated compounding device for parenteral nutrition 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 a separate parenteral nutrition container,* diluted, and used as an admixture in parenteral nutrition solution for intravenous infusion. See **Full Prescribing Information** for complete dosing and administration information.[1]

Multrys®

(trace elements injection 4*, USP)

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

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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 as part of an overall initiative to retire its line of unapproved trace element products. This change also provided the opportunity for American Regent to more closely align Multrys 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?**
    During product selection and development, we assessed the literature (as well as our previously marketed products) and Multrys more closely aligns 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]

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

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. 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 preciptates
- 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 adminstration in parenteral nutrition. For patients with cholestasis, bilary 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.

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.

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

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

References

1. Multrys® (trace elements injection 4*, USP). Package insert. American Regent, Inc.; 2021.

2. Questions about single-dose/single-use vials. Centers for Disease Control and Prevention. Updated June 20, 2019. Accessed July 6, 2023. 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. Accessed July 6, 2023. 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. 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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