

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 when oral or enteral nutrition is not possible.¹

2. What are the available dosage forms for Multrys?

Multrys is available as an injection in a 1 mL single dose vial.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 portion¹
- 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 admixture¹
- Protect the parenteral nutrition solution from light¹
- 5. I use an automated compounding device for parenteral nutrition (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 a separate parenteral nutrition container*, diluted, and used as an admixture in parenteral nutrition solution. See <u>Full Prescribing Information</u> for complete dosing and administration information.¹



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

7. Does Multrys contain any preservatives?

No. Multrys is preservative free.

8. Is Multrys latex-free?

Yes. 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 previously marketed products. In addition, Multrys is FDA approved.^{1,3}

11. Why is manganese included in the Multrys formulation?

During product selection and development, we assessed the literature and previously marketed products and more closely aligned Multrys with the 2012 ASPEN position paper, "Recommendations for Changes in Commercially Available Parenteral Multivitamin and Multi-Trace Element Products." Do not supplement Multrys with additional manganese.

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

References

- 1. Multrys® (trace elements injection 4*, USP) [package insert]. Shirley, NY: American Regent, Inc. 6/2021.
- Questions about single-dose/single-use vials. Centers for Disease Control and Prevention. Updated June 20, 2019. Accessed March 12, 2021. https://www.cdc.gov/injectionsafety/providers/provider_fags_singlevials.html.
- 3. Appropriate dosing for parenteral nutrition: ASPEN recommendations. American Society for Parenteral and Enteral Nutrition. 11/17/2020. Accessed March 12, 2021. http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines and Clinical Resources/PN%20Dosing%201-Sheet-FINAL.pdf.
- 4. Vanek 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 et al. A Call to Action to Bring Safer Parenteral Micronutrient Products to the US Market. Nutr Clin Pract. 2015;30(4):559-569.

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)

W 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

