

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.



Dosing and administration guide



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An FDA-approved multi-trace elements injection for neonatal and pediatric patients weighing less than 10 kg

Multrys™ (trace elements injection 4*, USP) 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.¹

- **Aligns with current treatment guidelines**

Multrys has been specifically developed to more closely align with the American Society for Parenteral and Enteral Nutrition (ASPEN) Dosing Recommendations for trace elements supplementation than previously marketed products²

- **Proven stability**

Stability studies support that Multrys can be safely stored for up to 9 days when added to the parenteral nutrition admixture and refrigerated¹

- **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

Each single-dose vial contains 1 mL. Each mL contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg.

For pediatric patients weighing 0.4 kg to 0.59 kg

- The 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 (please see Table 2)

For 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**
- The recommended volume of Multrys to be added to parenteral nutrition ranges from 0.2 mL per day to 1 mL **per day** based on body weight (please see Table 1)

Table 1. Recommended daily volume of Multrys and corresponding amount of each trace element (mcg)

| Body weight | Recommended daily volume | Amount of trace elements provided by the corresponding Multrys volume | | | |
|------------------|--------------------------|---|--------------|-----------------|----------------|
| | | Zinc (mcg) | Copper (mcg) | Manganese (mcg) | Selenium (mcg) |
| 0.6 kg to 0.8 kg | 0.2 mL | 200 mcg | 12 mcg | 0.6 mcg | 1.2 mcg |
| 0.9 kg to 1.1 kg | 0.3 mL | 300 mcg | 18 mcg | 0.9 mcg | 1.8 mcg |
| 1.2 kg to 1.4 kg | 0.4 mL | 400 mcg | 24 mcg | 1.2 mcg | 2.4 mcg |
| 1.5 kg to 1.7 kg | 0.5 mL | 500 mcg | 30 mcg | 1.5 mcg | 3 mcg |
| 1.8 kg to 2 kg | 0.6 mL | 600 mcg | 36 mcg | 1.8 mcg | 3.6 mcg |
| 2.1 kg to 2.3 kg | 0.7 mL | 700 mcg | 42 mcg | 2.1 mcg | 4.2 mcg |
| 2.4 kg to 2.6 kg | 0.8 mL | 800 mcg | 48 mcg | 2.4 mcg | 4.8 mcg |
| 2.7 kg to 2.9 kg | 0.9 mL | 900 mcg | 54 mcg | 2.7 mcg | 5.4 mcg |
| 3 kg to 9.9 kg | 1 mL | 1,000 mcg | 60 mcg | 3 mcg | 6 mcg |

Additional trace elements supplementation with Multrys™ (trace elements injection 4*, USP)

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

Multrys is recommended only for pediatric patients who require supplementation with all 4 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

Table 2. Daily requirement for trace elements supplementation for pediatric patients

| Trace elements | Patient weight (kg) | Daily requirement [†] |
|------------------------|---------------------|--------------------------------|
| Zinc | Less than 3 kg | 400 mcg/kg/day |
| | 3 kg to 5 kg | 250 mcg/kg/day |
| | 5 kg to 10 kg | 100 mcg/kg/day |
| Copper | — | 20 mcg/kg/day |
| Selenium | — | 2 mcg/kg/day |
| Manganese [‡] | — | 1 mcg/kg/day |

[†]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 with higher than the recommended dosage of 1 mcg/kg/day. Please see Warnings and Precautions in the [Full Prescribing Information](#).

For pediatric patients weighing less than 3 kg, Multrys does not provide the recommended daily dosage of zinc

- Zinc: For patients weighing less than 3 kg, add Zinc Sulfate to provide total daily recommended dose of 400 mcg/kg/day using parenteral and/or enteral routes of administration

For pediatric patients weighing 0.4 kg to 0.59 kg and 4 kg to 9.9 kg, Multrys does not provide the recommended daily dosage of copper or selenium

- Copper: For patients weighing 0.4 to 0.59 kg or 4 kg to 9.9 kg, add Cupric Chloride to provide total daily recommended dose of 20 mcg/kg/day using parenteral and/or enteral routes of administration
- Selenium: For patients weighing 0.4 to 0.59 kg or 4 kg to 9.9 kg, add Selenious Acid to provide total daily recommended dose of 2 mcg/kg/day using parenteral and/or enteral routes of administration

Monitoring

- Monitor zinc, copper, and selenium serum concentrations, whole blood manganese concentrations, fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count, and coagulation parameters. For patients with cholestasis or cirrhosis, monitor hepatic and biliary function during long-term administration of Multrys

Multrys is contraindicated in patients with hypersensitivity to zinc or copper. The following adverse reactions were identified in clinical studies or post-marketing reports: Neurologic toxicity with manganese, hepatic accumulation of copper and manganese, and hypersensitivity reactions with zinc and copper.

Administration information

Multrys is supplied as a single-dose vial 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.

The final parenteral nutrition solution is for intravenous infusion into a central or peripheral vein. The choice of a central or peripheral venous route should depend on the osmolarity of the final infusate. Solutions with osmolarity of 900 mOsmol/L or greater must be infused through a central catheter.

Intrinsic values for automated compounding devices for parenteral nutrition (PN) preparations

| Intrinsic value | Multrys |
|------------------|--------------|
| Osmolarity | 39 mOsmol/L |
| Specific gravity | 1.004 (g/mL) |
| pH range | 1.5-3.5 |

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

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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

DOSING 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 or by calling 1-800-FDA-1088.

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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:

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. American Society for Parenteral and Enteral Nutrition. Appropriate dosing for parenteral nutrition: ASPEN Recommendations. November 17, 2020. Accessed September 15, 2021. http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-FINAL.pdf
2. Multrys™ (trace elements injection 4*) [package insert]. Shirley, NY: American Regent, Inc. 6/2021.



AMERICAN REGENT®

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