AMERICAN REGENT™

American Regent Launches

Multrys™

(trace elements injection 4*, USP)

Multrys™ is supplied as a 1 mL single dose vial.
*Each mL contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg.

Multrys™ is the first and only FDA-Approved multiple trace element injection for neonatal and pediatric patients less than 10 kg.[1]

Melville, NY – September 2, 2021: American Regent, Inc. introduces FDA-approved Multrys™ (trace elements injection 4*, USP). Multrys™ is 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.[2] View more product specific information.

"We are pleased to offer another FDA-approved multiple trace elements injection specifically developed to more closely align with the American Society for Parenteral and Enteral Nutrition (ASPEN) recommendations for trace element supplementation.[3] This new formulation, which is manufactured in America, has been designed to meet the special needs of the neonatal and pediatric patient population and is part of our overall initiative to retire our line of marketed unapproved trace element products," stated Joann Gioia, Vice President and Chief Commercial Officer at American Regent, Inc. "The launch of Multrys™ demonstrates American Regent's continued commitment to addressing the needs of patients who require trace element supplementation."

This product is available for immediate shipment. Customers can order Multrys™ through their wholesaler/distributor, or by contacting our Customer Support Group at 1-800-645-1706.

Multrys™ (trace elements injection 4*, USP) is supplied as follows:

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

Please see the Important Safety Information below. To view the Full Prescribing Information, please click here. For additional information on Multrys visit www.americanregent.com.

References
1. US Food and Drug Administration, Center for Drug Evaluation and Research. Multrys™ NDA 209376/S-002 Approval Letter, June 30, 2021. **2.** Multrys™ (trace elements injection 4*) [package insert]. Shirley, NY: American Regent, Inc.; 2021. **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.

PP-MU-US-0012 8/2021

265 Broadhollow Road \\ 4th Floor \\ Melville, NY 11747
T 631.924.4000 \\ **F** 631.924.1731 \\ americanregent.com

A Daiichi Sankyo Group Company

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

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

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.

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.

REF-1826 6/2021

You are encouraged to report Adverse Drug Events (ADEs) to American Regent:

Email: pv@americanregent.com; **Fax:** 1-610-650-0170;
Phone: 1-800-734-9236

ADEs may also be reported to the FDA:
1-800-FDA-1088 or to www.fda.gov/medwatch

Drug Information:
1-888-354-4855
(9:00 am – 5:00 pm Eastern Time, Monday – Friday)
www.americanregent.com

For urgent drug information outside of normal business hours,
that cannot wait until the next business day
1-877-845-6371

About American Regent

American Regent, Inc., a Daiichi Sankyo Group company, is a leading injectable manufacturer. For over 50 years, American Regent has been developing, manufacturing and supplying quality generic and branded injectables for healthcare providers. For nearly 20 years, we have been a leader in IV iron therapy.

American Regent is committed to US based manufacturing. To that end, over the last several years, we have made significant investments in expanding and modernizing our manufacturing facilities in Ohio and New York. This expansion will nearly double our capacity and allow us to better serve our customers now and in the future.

Speed counts. Flexibility matters. Reliability and quality are paramount. Because patients should never have to wait for the medications they need.

For more information, please visit www.americanregent.com.

About Daiichi Sankyo Group

Daiichi Sankyo is dedicated to creating new modalities and innovative medicines by leveraging our world-class science and technology for our purpose "to contribute to the enrichment of quality of life around the world." In addition to our current portfolio of medicines for cancer and cardiovascular disease, Daiichi Sankyo is primarily focused on developing novel therapies for people with cancer as well as other diseases with high unmet medical needs. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation to realize our 2030 Vision to become an "Innovative Global Healthcare Company Contributing to the Sustainable Development of Society." For more information, please visit www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is a member of the Daiichi Sankyo Group.

For more information on Daiichi Sankyo, Inc., please visit: www.dsi.com