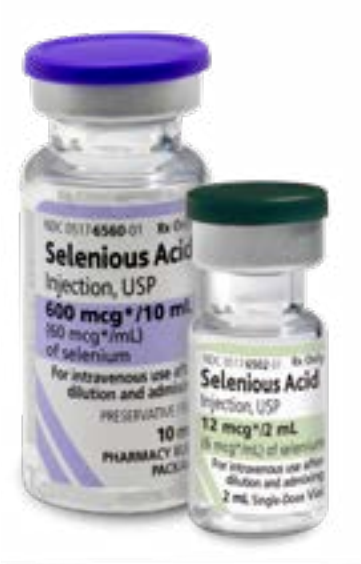
Selenious Acid

Injection, USP

Dosing and administration guide



Selenious Acid
Injection, USP

American Regent offers Selenious Acid Injection, USP in 2 strengths to meet your patients' needs.

Selenious Acid Injection, USP is a trace element indicated for adult and pediatric patients as a source of selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated.

- **Designed to meet the needs of neonatal, pediatric, and adult patients**

  The 12 mcg/2 mL (6 mcg/mL of selenium) concentration is available as a single-dose vial for the treatment of neonatal and pediatric patients weighing less than 7 kg.[1]

  Also available in a 600 mcg/10 mL (60 mcg/mL of selenium) pharmacy bulk package vial for the treatment of adult and pediatric patients.[1]

  Important medication safety note: there is a 10 times concentration difference between the two products.

- **Aligns with current treatment guidelines**

  Selenious Acid Injection, USP aligns with the American Society for Parenteral and Enteral Nutrition (ASPEN) Dosing Recommendations for trace elements supplementation *(please refer to the Selenious Acid Injection, USP dosing chart on page 4)*.[2]

  ASPEN recommends that the parenteral selenium intake should be[2]:
  - 60 to 100 mcg/day for adults
  - 2 mcg/kg/day for pediatric patients weighing up to 10 kg
  - 2 mcg/kg/day (maximum of 100 mcg/day) for pediatric patients weighing 10 to 40 kg

ASPEN recommends that selenium be routinely added to PN formulations. This can be accomplished by using either a multiple trace element product, such as Tralement® (trace elements injection 4*, USP), Multrys™ (trace elements injection 4*, USP), or an individual trace element such as Selenious Acid Injection, USP. Multrys and Tralement are indicated only for patients who require all 4 trace elements.

Specifically, use with patients on PN who are NPO and/or cannot ingest or absorb nutrients via their GI tract.[2]

*Each mL of **Multrys** contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg. Each mL of **Tralement** contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg.

- **Proven stability**

  Stability studies support that both concentrations of our Selenious Acid Injection, USP can be safely stored for up to 9 days when added to the parenteral nutrition admixture and refrigerated.[1]

  Please immediately discard any unused drug from the single-dose vial. Please discard within 4 hours any unused drug from the pharmacy bulk package vial.[1]

- **Consistent supply**

  Selenious Acid Injection, USP 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.

- **Recognizing selenium deficiency**

  Signs and symptoms of selenium deficiency include cardiomyopathy, myalgias, myositis, anemia, hemolysis, and impaired cellular immunity.[3]

Additional considerations

Monitor selenium concentrations, fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters throughout treatment.

Multrys and Tralement:
Monitor 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.

GI=gastrointestinal; NPO=nothing by mouth; PN=parenteral nutrition.

Recommended dosage of Selenious Acid Injection, USP for adults and pediatric patients by estimated weight from the product's Full Prescribing Information[1]

Population	Recommended dosage
Adults	60 mcg/day
Pediatric patients 7 kg and above	2 mcg/kg/day (up to 60 mcg/day)
Pediatric patients less than 7 kg	2 to 4 mcg/kg/day

The dosages in the above table are general recommendations intended for most patients. However, based on clinical requirements, some patients may require a higher dosage. The dosage of Selenious Acid Injection, USP should be individualized based on the patient's clinical condition, nutritional requirements, and the contribution of oral or enteral selenium intake.

Select patients may need additional supplementation with selenium even when taking a selenium-containing product such as Tralement® (trace elements injection 4*, USP) or Multrys™ (trace elements injection 4*, USP)

Multrys†	Select patients who have Multrys in their PN preparations may need additional supplementation with individual trace elements. For example: Pediatric patients weighing 0.4 kg to 0.59 kg and 4 kg to 9.9 kg—Multrys does not provide the daily dosage of selenium.[4] To learn more about how to properly dose Multrys, please see section 2.5 of the Full Prescribing Information.
Tralement	Select patients who have Tralement in their PN preparations may need additional supplementation with individual trace elements. For example: Pediatric patients weighing 10 kg to 49 kg—additional selenium may be needed to meet the recommended daily dosage.[5] To learn more about how to properly dose Tralement, please see section 2.5 of the Full Prescribing Information.

*Each mL of **Multrys** contains zinc 1,000 mcg, copper 60 mcg, manganese 3 mcg, and selenium 6 mcg. Each mL of **Tralement** contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg.

†Multrys is not recommended for pediatric patients who may require a lower dosage of 1 or more of these individual trace elements. Multrys is recommended only for pediatric patients who require supplementation with all 4 of the individual trace elements (ie, zinc, copper, manganese, and selenium).

Dosing considerations

The dosage of the final parenteral nutrition solution containing Selenious Acid Injection, USP must be based on the concentrations of all components in the solution and the recommended daily nutritional requirements.

Before administration of parenteral nutrition solution containing Selenious Acid Injection, USP, correct severe fluid, electrolyte, and acid-base disorders.

Monitoring

Monitor selenium concentrations, fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters throughout treatment.

Select administration information

Selenious Acid Injection, USP is supplied as a pharmacy bulk package or single-dose vial for *admixing use* only. *It is not for direct intravenous infusion*. Prior to administration, Selenious Acid Injection, USP must be transferred to a separate parenteral nutrition container, prepared and used as an admixture in parenteral nutrition solutions.

Select preparation instructions

Selenious Acid Injection, USP is to be prepared only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area). Visually inspect the prepared parenteral nutrition solution containing Selenious Acid Injection, USP for particulate matter before admixing, after admixing, and prior to administration. Transfer Selenious Acid Injection, USP to the parenteral nutrition solution following the admixture of amino acids, dextrose, lipid (if added), and electrolytes solutions.

Intrinsic values for automated compounding devices for PN preparations

Intrinsic value	Selenious Acid 600 mcg/10 mL	Selenious Acid 12 mcg/2 mL
Osmolarity	16 mOsmol/L	13 mOsmol/L
Specific gravity	1.000 (g/mL)	1.000 (g/mL)
pH range	1.8 to 2.4	1.8 to 2.4

For complete information, including dosing and administration, please see the Full Prescribing Information.

Selenious Acid
Injection, USP

For intravenous use

INDICATIONS AND USAGE
Selenious Acid Injection is indicated in adult and pediatric patients as a source of selenium for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Important Administration Information
Pharmacy Bulk Package or Single Dose Vial: *Not for direct intravenous infusion*.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
None

WARNINGS AND PRECAUTIONS
Pulmonary Embolism due to Pulmonary Vascular Precipitates: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation.

Vein Damage and Thrombosis: Selenious Acid Injection has a low pH and must be prepared and used as an admixture in PN solutions. Solutions with osmolarity of 900 mOsm/L or more must be infused through a central venous catheter.

Aluminum Toxicity: Selenious Acid Injection contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Preterm infants are particularly at risk for aluminum toxicity because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which also contain aluminum.

Monitoring and Laboratory Tests: Monitor selenium concentrations, fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters throughout treatment.

ADVERSE REACTIONS
No selenium-related adverse reactions have been reported in clinical studies or postmarketing reports in patients receiving intravenously administered PN solutions containing selenious acid within the recommended dosage range.

USE IN SPECIFIC POPULATIONS

Pregnancy: Risk Summary: Administration of the recommended dose of Selenious Acid Injection in PN is not expected to cause major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation: Risk Summary: Selenium is present in human milk. There is no information on the effects of selenious acid on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Selenious Acid Injection and any potential adverse effects on the breastfed infant from Selenious Acid Injection or from the underlying maternal condition.

Pediatric Use: Safety and dosing recommendations in pediatric patients are based on clinical experience.

Geriatric Use: Dose selection should be individualized based on the patient's clinical condition, nutritional requirements, and additional nutritional intake provided orally or enterally to the patient.

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-1167 10/2021

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

Tralement®

(trace elements injection 4*, USP)

*Each mL contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg.

For intravenous use

INDICATIONS AND USAGE

Tralement® is indicated in adult and pediatric patients weighing at least 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

Important Administration Information

Tralement is supplied as a single-dose vial for *admixture use* only. It is *not for direct intravenous infusion*. Prior to administration, Tralement *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 Tralement, correct severe fluid, electrolyte, and acid-base disorders.
- The dosage of the final parenteral nutrition solution containing Tralement must be based on the concentrations of all components in the solution, the patient's clinical condition, nutritional requirements, and the contribution of oral or enteral intake.

  Tralement is recommended only for patients who require supplementation with all four of the individual trace elements (i.e., zinc, copper, manganese and selenium).

  See Full Prescribing Information on preparation, administration and dosing.

CONTRAINDICATIONS

Tralement is 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 infusion and initiate a medical evaluation.
- Vein Damage and Thrombosis: Solutions with osmolarity of 900 mOsmol/L or more must be infused through a central catheter. The primary complication of peripheral access is venous thrombophlebitis.
- Neurologic Toxicity with Manganese: Monitor patients receiving long-term parenteral nutrition solutions containing Tralement for neurologic signs and symptoms and routinely monitor whole blood manganese concentrations and liver function tests. Discontinue Tralement and consider brain magnetic resonance imaging (MRI) if toxicity suspected.
- Hepatic Accumulation of Copper and Manganese: Assess for development of hepatic or biliary dysfunction. Monitor concentrations of copper and manganese in patients with cholestasis, biliary dysfunction or cirrhosis receiving Tralement long-term.

- Aluminum Toxicity: Tralement contains aluminum that may be toxic. Increased risk in patients with renal impairment, including preterm infants.
- Monitoring and Laboratory Tests: Monitor blood zinc, copper, manganese, and selenium concentrations, fluid and electrolyte status, serum osmolarity, blood glucose, liver and kidney function, blood count and coagulation parameters.
- Hypersensitivity Reactions with Zinc and Copper: If reactions occur, discontinue Tralement 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, and 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, and hypersensitivity reactions with zinc and copper

USE IN SPECIFIC POPULATIONS

Pregnancy - Risk Summary - Deficiency of trace elements may result in adverse pregnancy and fetal outcomes.

Lactation - Risk Summary - Zinc, copper, manganese, and selenium are present in human milk. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Tralement and any potential adverse effects on the breastfed infant from Tralement or from the underlying maternal condition.

Pediatric Use - Refer to Full Prescribing Information for dosing. Do not supplement Tralement with additional manganese. Tralement is not approved for use in pediatric patients weighing less than 10 kg.

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 Tralement.

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.

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-1535 2/2021

Selenious Acid
Injection, USP

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. Selenious Acid Injection, USP. Package insert. American Regent, Inc.; 2021.
2. American Society for Parenteral and Enteral Nutrition. Appropriate dosing for parenteral nutrition: ASPEN Recommendations. November 17, 2020. Accessed January 5, 2022. http://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-FINAL.pdf
3. Jensen GL, Binkley J. Clinical manifestations of nutrient deficiency. *JPEN J Parenter Enteral Nutr*. 2002;26(suppl 5):S29-S33.
4. Multrys™ (trace elements injection 4*, USP). Package insert. American Regent, Inc.; 2021.
5. Tralement® (trace elements injection 4*, USP). Package insert. American Regent, Inc.; 2020.

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