Introduction of Tralement®, the first and only FDA-approved multi-trace element injection for parenteral nutrition.

Tralement® (trace elements injection 4®, USP) has been specifically developed to align with the ASPEN recommendations for trace element supplementation. The concentration of each element in new Tralement® has been formulated to meet the needs of a broad range of pediatric and adult patients.1,2

- Aligns with Current Treatment Guidelines Tralement® has been specifically developed to align with the ASPEN recommendations for trace element supplementation. The concentration of each element in new Tralement® has been formulated to meet the needs of a broad range of pediatric and adult patients.1,2

- Dosing: Added to Parenteral Nutrition A 1 mL dose of Tralement® per day for adults and pediatric patients weighing at least 50 kg simplifies treatment planning and for healthcare workers, may save time and may reduce the likelihood of errors.1,2 Weight-dependent dosing is provided for pediatric patients between 10 kg to 49 kg. Tralement® is not recommended for patients who may require a lower dosage of one or more of the individual trace elements.

- Proven Safety Stability studies support Tralement® can be safely stored for up to 9 days when added to the parenteral nutrition admixture and refrigerated.2

- Consistent Supply Tralement® is proudly manufactured in America. American Regent is committed to providing a consistent supply to help ensure that your patient care needs are met.

ADULT TRACE ELEMENT DOSING

<table>
<thead>
<tr>
<th>Trace Element</th>
<th>Tralement® per 1 mL</th>
<th>Multitrace®-4 Neonatal</th>
<th>Multitrace®-4 Neonatal</th>
<th>Multitrace®-4 Concentrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc</td>
<td>3.5 mg</td>
<td>3.5 mg</td>
<td>3.5 mg</td>
<td>3.5 mg</td>
</tr>
<tr>
<td>Copper</td>
<td>0.35 mg</td>
<td>0.3 mg</td>
<td>0.3 mg</td>
<td>0.3 mg</td>
</tr>
<tr>
<td>Manganese</td>
<td>55 mcg</td>
<td>55 mcg</td>
<td>55 mcg</td>
<td>55 mcg</td>
</tr>
<tr>
<td>Selenium</td>
<td>60-100 mcg</td>
<td>60 mcg</td>
<td>60 mcg</td>
<td>60 mcg</td>
</tr>
<tr>
<td>Chromium</td>
<td>&lt;1 mg</td>
<td>0 mcg</td>
<td>0 mcg</td>
<td>0 mcg</td>
</tr>
</tbody>
</table>

Refer to the table below for specifications on Tralement® as it compares to the select unapproved trace element products offered by American Regent. For additional information, visit www.americanregent.com.

AMERICAN REGENT TRACE ELEMENT PRODUCTS SPECIFICATIONS

<table>
<thead>
<tr>
<th>Product</th>
<th>Tralement®</th>
<th>Multitrace®-4 Neonatal</th>
<th>Multitrace®-4 Neonatal</th>
<th>Multitrace®-4 Concentrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Status</td>
<td>FDA Approved</td>
<td>Marketed Unapproved</td>
<td>Marketed Unapproved</td>
<td>Marketed Unapproved</td>
</tr>
<tr>
<td>Availability</td>
<td>New and Available</td>
<td>Available</td>
<td>Available</td>
<td>Discontinued</td>
</tr>
<tr>
<td>Strength</td>
<td>N/A</td>
<td>Neonatal</td>
<td>Pediatric</td>
<td>Concentrate</td>
</tr>
<tr>
<td>Trace Elements per mL</td>
<td>zinc 2 mg</td>
<td>copper 0.3 mg</td>
<td>manganese 15 mcg</td>
<td>selenium 60 mcg</td>
</tr>
<tr>
<td>Vial Type</td>
<td>Single Dose Vial</td>
<td>Single Dose Vial</td>
<td>Single Dose Vial</td>
<td>Single Dose Vial</td>
</tr>
<tr>
<td>Fill Volume</td>
<td>1 mL</td>
<td>2 mL</td>
<td>3 mL</td>
<td>1 mL</td>
</tr>
<tr>
<td>Preservative</td>
<td>Preservative Free</td>
<td>Preservative Free</td>
<td>Preservative Free</td>
<td>Preservative Free</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.003 (g/mL)</td>
<td>1.004 (g/mL)</td>
<td>1.015 (g/mL)</td>
<td></td>
</tr>
<tr>
<td>Cap Color</td>
<td>Garnet</td>
<td>Salmon</td>
<td>Pink</td>
<td>Orange</td>
</tr>
<tr>
<td>Aluminum Content</td>
<td>No more than 6,000 mcg of Aluminum</td>
<td>No more than 6,250 mcg of Aluminum</td>
<td>No more than 6,250 mcg of Aluminum</td>
<td></td>
</tr>
<tr>
<td>Package Size</td>
<td>25</td>
<td>25</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>Storage</td>
<td>Store at 20°C to 25°C</td>
<td>Store at 20°C to 25°C</td>
<td>Store at 20°C to 25°C</td>
<td></td>
</tr>
<tr>
<td>Trace Element Stability in TPN</td>
<td>Up to 9 days when added to the PN admixture and refrigerated</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

Phone: 1-800-653-1082 Fax: 1-631-440-2310

ADEs may also be reported to the FDA:

1-888-FDA-1082 or www.fda.gov/medwatch

Drug Information:

1-866-354-4855 (9:00 AM – 5:00 PM Eastern Time, Monday – Friday)

For urgent drug information outside of normal business hours, assistance is available at 1-877-845-6371

Innate Pharmacology

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.1

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 final dose of the 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-Venous Thromboembolism: If signs of pulmonary distress occur, stop the infusion and institute a medical evaluation.
- Acute and Chronic Thromboembolic Disease: Solutions with osmolarity greater than 900 mOsm/L and/or pH outside the range of 4.5 to 9.2 may increase the risk of thromboembolic disease.
- Hypersensitivity Reactions with Zinc and Copper: If a reaction occurs, discontinue Tralement and institute appropriate medical treatment.

ADVERSE REACTIONS

The following adverse reactions were identified in clinical studies or postmarketing reports. Given that some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate that frequency or establish a causal relationship to drug exposure.

Adverse reactions with other components of parenteral nutrition solutions:

- Pulmonary emboli due to pulmonary venous thromboembolism
- Vein damage and thrombosis
- Aluminum toxicity

Adverse reactions with the use of trace elements and multivitamins

- Neurologic toxicity with manganese
- Hypocomplementemia with copper and manganese
- Hyperparathyroidism with zinc and copper

USING IN SPECIFIC POPULATIONS

Pregnancy - Risk Summary: Deficiency of trace elements may result in abnormal 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 before dosing.

OVERDOSAGE - There are reports on overdose in the literature for the individual trace elements. Management of overdose is supportive care based on presenting signs and symptoms. For additional safety information, please see Full Prescribing Information.

References

1. Approved Drug Products with Therapeutic Equivalence Evaluations: https://www.fda.gov/Drugs/RetailDrugDisplay/ (Updated 8 August, 2020)
2. Tralement™ (trace elements injection 4®, USP) [package insert]; Shirley, NY: American Regent, Inc.; 18 June 2018
3. American Society for Parenteral and Enteral Nutrition (ASPEN) website: www.aspentrust.org

TRALEMENT is a trademark of American Regent, Inc. Patients protected by US patent 10,941,952.