

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

This is to inform you that the following Lot No.'s 25149 and 25371 of Tralement (trace elements injection 4*, USP) manufactured and distributed by American Regent, Inc. is the subject of a Recall. Recall of this product to RETAIL LEVEL was initiated due to particulate found during Reject Characterization.

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.

The administration of an injectable product containing particulate matter could potentially result in phlebitis, capillary occlusion, thromboembolism, or an immunologic or immunogenic response. When Tralement (trace elements injection 4*, USP) is used according to the approved prescribing procedures, at this time there is low potential risk of the particle entering the systemic circulation with consequent adverse reactions. As of July 24, 2026, American Regent, Inc. has not received any reports of adverse events related to this recall.

PRODUCT RECALL: Tralement (trace elements injection 4*, USP) *Each mL contains zinc 3 mg, copper 0.3 mg, manganese 55 mcg, and selenium 60 mcg

NDC NUMBER: 0517-9305-25

Lot No: 25149

Expiration Date: April 30, 2027

Lot No: 25371

Expiration Date: September 30, 2027