

June 1, 2021

Dear Healthcare Professional,

As part of our ongoing efforts to develop FDA approved products to align with the American Society for Parenteral and Enteral (ASPEN) guidelines, American Regent has voluntarily decided to cease manufacturing of Multitrace[®]-4 Pediatric (trace element injection 4, USP). *We estimate that supply of this product will be available until late July 2021.*

American Regent is committed to providing appropriate trace element supplementation to patients requiring parenteral nutrition. We have demonstrated this by launching Tralement[®] (trace elements injection 4*), a trace element supplement that may be used in patients 10 kg and above. In addition, we are developing a new trace element formulation for patients under 10 kg that we hope to launch in the early Fall.

In the meantime, we are committed to ensuring an adequate, consistent supply of Tralement[®] and Multitrace[®]-4 Neonatal (trace elements injection 4, USP) until we have launched an approved trace element formulation that can meet the needs of patients weighing less than 10 kg.

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Product Name	Tralement®		Multitrace [®] -4 Neonatal		Multitrace [®] -4 Pediatric	
Pack NDC	0517-9305-25		0517-6202-25		0517-9203-25	
Marketing Status	FDA Approved		Marketed Unapproved		Marketed Unapproved	
Availability Status	Available		Available		Estimated availability until late July 2021 [†]	
Vial Size	1 mL		2 mL		3 mL	
Trace Elements Content per/mL	Zinc	3 mg	Zinc	1.5 mg	Zinc	1 mg
	Copper	0.3 mg	Copper	0.1 mg	Copper	0.1 mg
	Manganese	55 mcg	Manganese	25 mcg	Manganese	25 mcg
	Selenium	60 mcg	Chromium	0.85 mcg	Chromium	1 mcg
Full Prescribing Information	<u>Tralement®</u>		Multitrace [®] -4 Neonatal		Multitrace [®] -4 Pediatric	

The table below provides a quick reference to the products noted above.

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

⁺Multitrace[®]-4 Pediatric is estimated to be available until late July 2021, or until supply has been depleted.

For additional information on managing the Multitrace[®]-4 Pediatric inventory transition and to sign up for timely updates on the inventory transition, <u>click here</u>.



For assistance in transitioning your patients to either the Multitrace[®]-4 Neonatal product or Tralement[®], please contact our medical affairs team at <u>888-354-4855</u> or <u>www.americanregent.com/medical-affairs</u>"

You are encouraged to report Adverse Drug Events to American Regent, Inc. at 1-800-734-9236, or to the FDA by visiting <u>www.fda.gov/medwatch</u> or calling 1-800-FDA-1088.

Sincerely,

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Syed Numan, MD, M.B.A, PMP Medical Director, Head of Medical Affairs American Regent, Inc.

 ${\sf Tralement}^{\circledast}$ is a Registered Trademark of American Regent, Inc. Patents pending. @ American Regent, Inc.