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Pfizer Inc.
275 North Field Drive
Lake Forest, IL 60045



August 21, 2023

**NDC and Labeling Change for Linezolid Injection in 0.9% Sodium Chloride
600 mg/300 mL (2 mg/mL) Single-dose Container**

Dear Valued Customer,

Pfizer Hospital is pleased to share that the new NDC, with a labeling change, **Linezolid Injection in 0.9% Sodium Chloride 600 mg/300 mL (2 mg/mL) Single-dose Container** is now available at wholesaler and distributors (please note locational inventory may vary).

While there is a difference in packaging, and product label, as detailed in the Product Information Table below, please note there is no change to the unit of sale size, formulation, or indication.

Please keep in mind that as we transition to the new NDC, 00409-4883-10, both labels will be in the marketplace temporarily. However, until it is depleted, we request that you continue using the current NDC, 00409-4883-01, when available.

TRANSITION TABLE

CURRENT NDC	NEW NDC INFORMATION			
Unit of Sale NDC Being Depleted	Unit of Sale NDC Being Made Available	Ordering & Shipping Options	Product Description	Unit of Sale Pack Size
00409-4883-01	00409-4883-10	Wholesaler, Distributor & Direct Ship	Linezolid Injection in 0.9% Sodium Chloride 600 mg/300 mL (2 mg/mL) Single-dose Container	10




Wholesaler numbers and barcodes have been included below in preparation for ordering the new NDC presentation.

WHOLESALE NUMBER TABLE



NEW NDC Wholesaler Numbers					
NEW Unit of Sale NDC	NEW Unit of Use NDC	ABC	Cardinal	McKesson	Morris & Dickson
00409- 4883-10	00409- 4883-03	10280845	5855887	2830271	290981

BARCODES – NEW NDC

Please note the new foil overwrap has a different barcode than the Unit of Use.

Linezolid Injection in 0.9% Sodium Chloride 600 mg/300 mL (2 mg/mL) Single-dose Container Unit of Sale	Linezolid Injection in 0.9% Sodium Chloride 600 mg/300 mL (2 mg/mL) Single-dose Container Unit of Use	Linezolid Injection in 0.9% Sodium Chloride 600 mg/300 mL (2 mg/mL) Single-dose Container Foil Overwrap (Interpack)
		
00304094883106	10304094883035	20304094883032

PRODUCT INFORMATION

CATEGORY	CURRENT	NEW
Product Description	Linezolid Injection in 0.9% Sodium Chloride 600 mg/300 mL (2 mg/mL) VisIV™ Flexible Container	Linezolid Injection in 0.9% Sodium Chloride 600 mg/300 mL (2 mg/mL) Single-dose Container
Unit of Sale NDC	00409-4883-01	00409-4883-10
Unit of Use NDC	00409-4883-11	00409-4883-03
Unit of Use Bag Image		

CATEGORY	CURRENT	NEW
Unite of Use Label Image	<p>300 mL NDC 0409-4883-11</p> <p>Linezolid Injection in 0.9% Sodium Chloride</p> <p>600 mg/300 mL (2 mg/mL)</p> <p>For Intravenous Infusion</p> <p>EACH mL CONTAINS LINEZOLID, 2 MG; CITRIC ACID ANHYDROUS, USP, 1.92 MG; SODIUM HYDROXIDE, 0.76 MG; SODIUM CHLORIDE, USP 9 MG IN WATER FOR INJECTION. ADJUST pH TO 4.4 - 5.2 WITH SODIUM HYDROXIDE AND/OR HYDROCHLORIC ACID.</p> <p>STERILE AND NON-PYROGENIC. SINGLE-DOSE CONTAINER. DOSAGE AND USE: SEE INSERT. STORE AT 20 TO 25°C (68 TO 77°F). EXCURSIONS PERMITTED TO 15 TO 30°C (59 TO 86°F). [SEE USP CONTROLLED ROOM TEMPERATURE.] PROTECT FROM FREEZING. LINEZOLID IS SENSITIVE TO LIGHT. RETAIN IN OVERWRAP PRIOR TO USE. USE ONLY IF SOLUTION IS CLEAR AND CONTAINER IS UNDAMAGED. MUST NOT BE USED IN SERIES CONNECTIONS. VisiV IS A TRADEMARK OF HOSPIRA. DO NOT REMOVE CAPS UNTIL READY FOR USE. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED.</p> <p>VisiV™ Container</p> <p>Rx ONLY</p> <p>IM-5097</p> <p>HOSPIRA, INC., LAKE FOREST, IL 60045 USA</p> <p>Hospira</p> <p>5 PP</p>	<p>300 mL NDC 0409-4883-03</p> <p>Linezolid Injection in 0.9% Sodium Chloride</p> <p>600 mg/300 mL (2 mg/mL)</p> <p>For Intravenous Infusion</p> <p>Each mL contains Linezolid 2 mg; Citric Acid anhydrous, USP, 1.92 mg; Sodium Hydroxide, 0.76 mg; Sodium Chloride, USP 9 mg in Water for injection. Adjust pH to 4.4 - 5.2 with Sodium Hydroxide and/or Hydrochloric Acid.</p> <p>Sterile and non-pyrogenic. Single-dose container. Recommended Dosage: See Prescribing Information. Store at 20 to 25°C (68 to 77°F). Excursions permitted to 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.] Protect from freezing. Linezolid is sensitive to light. Use only if solution is clear and container is undamaged. Must not be used in series connections. Do not remove caps until ready for use. If leaks are found, discard solution as sterility may be impaired.</p> <p>Rx ONLY</p> <p>Distributed by Hospira, Inc. Lake Forest, IL 60045 USA</p> <p>LOT</p> <p>EXP</p> <p>1234567890 FUU 07233 01-68-12-028</p> <p>OTHER SET</p> <p>YYMMDDUOO MM/YYYY</p>
Foil Overwrap Image (Interpack)	<p>Each mL contains Linezolid, 2 mg; Citric Acid Anhydrous, USP, 1.92 mg; Sodium Hydroxide, 0.76 mg; Sodium Chloride, USP 9 mg in Water for injection. pH adjusted to 4.4 - 5.2 with Sodium Hydroxide and/or Hydrochloric Acid.</p> <p>Single-dose container. Discard unused portion. Dosage and Use: see insert.</p> <p>Do not use in series connections. The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Visually inspect overwrap for tears or holes. Discard unit if overwrap is damaged or if solution is discolored in any way. Use unit promptly when overwrap is opened. Store at 20 to 25°C (68 to 77°F). Excursions permitted to 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.] Do not freeze. Linezolid is sensitive to light. Retain overwrap prior to use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.</p> <p>Rx only</p> <p>300 mL NDC 0409-4883-11</p> <p>Linezolid Injection in 0.9% Sodium Chloride</p> <p>600 mg/300 mL (2 mg/mL)</p> <p>For Intravenous Infusion</p> <p>Single-dose container</p> <p>F WR-1532</p> <p>Hospira, Inc., Lake Forest, IL 60045 USA</p> <p>Hospira</p>	<p>300 mL NDC 0409-4883-03</p> <p>Linezolid Injection in 0.9% Sodium Chloride</p> <p>600 mg/300 mL (2 mg/mL)</p> <p>For Intravenous Infusion • Single-dose container</p> <p>Each mL contains Linezolid, 2 mg; Citric Acid anhydrous, USP, 1.92 mg; Sodium Hydroxide, 0.76 mg; Sodium Chloride, USP 9 mg in Water for injection. pH adjusted to 4.4 - 5.2 with Sodium Hydroxide and/or Hydrochloric Acid.</p> <p>Discard unused portion. Recommended Dosage: See Prescribing Information.</p> <p>The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Visually inspect overwrap for tears or holes. Discard unit if overwrap is damaged or if solution is discolored in any way. Use unit promptly when overwrap is opened.</p> <p>Store at 20 to 25°C (68 to 77°F). Excursions permitted to 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.] Do not freeze. Rx only</p> <p>Linezolid is sensitive to light. After removing the overwrap, check bag for minute leaks by squeezing container firmly.</p> <p>If leaks are found, discard solution as sterility may be impaired.</p> <p>MADE IN SINGAPORE</p> <p>Distributed by Hospira Inc., Lake Forest, IL 60045 USA</p> <p>LOT:</p> <p>EXP:</p> <p>1234567890 FUU 07233 01-78-12-033</p>
Foil Overwrap Label (Interpack)	Same as Above	<p>300 mL NDC 0409-4883-03</p> <p>Linezolid Injection in 0.9% Sodium Chloride</p> <p>600 mg/300 mL (2 mg/mL)</p> <p>For Intravenous Infusion • Single-dose container</p> <p>TO OPEN — TEAR AT NOTCH</p> <p>Each mL contains Linezolid, 2 mg; Citric Acid anhydrous, USP, 1.92 mg; Sodium Hydroxide, 0.76 mg; Sodium Chloride, USP 9 mg in Water for Injection. pH adjusted to 4.4 - 5.2 with Sodium Hydroxide and/or Hydrochloric Acid.</p> <p>Discard unused portion. Recommended Dosage: See Prescribing Information.</p> <p>The overwrap is a moisture barrier. Do not remove unit from overwrap until ready for use. Visually inspect overwrap for tears or holes. Discard unit if overwrap is damaged or if solution is discolored in any way. Use unit promptly when overwrap is opened.</p> <p>Store at 20 to 25°C (68 to 77°F). Excursions permitted to 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature.] Do not freeze. Rx only</p> <p>Linezolid is sensitive to light. After removing the overwrap, check bag for minute leaks by squeezing container firmly.</p> <p>If leaks are found, discard solution as sterility may be impaired.</p> <p>MADE IN SINGAPORE</p> <p>Distributed by Hospira Inc., Lake Forest, IL 60045 USA</p> <p>LOT:</p> <p>EXP:</p> <p>YYMMDDUOO MM/YYYY</p> <p>1234567890 FUU 07233 01-78-12-033</p>

CATEGORY	CURRENT	NEW
Unit of Sale Shipper Label	<p>NDC 0409-4883-01 L/N 4883-01 LC 04 IC 01 CASE PACK 1 X 10-300 ML LINEZOLID INJECTION IN 0.9% SODIUM CHLORIDE 600 MG/300 ML (2 MG/ML) VisIV™ Rx only</p> <p>Store at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature.]</p> <p>Distributed by Hospira, Inc., Lake Forest, IL 60045 USA</p> <p>MADE IN TAIWAN</p> <p>LOT NO. [LOTNUM] QTY 1 EXP. DATE [EXPDATE]</p> <p>(17)123456(10)12345AB(30)01</p> <p>(01)20304094883018(21)123456789012</p> <p>PAA180473 LOAD [LOADNUM]</p>	<p>NDC 0409-4883-10 CASE PACK 1 X 10-300 ML LINEZOLID INJECTION IN 0.9% SODIUM CHLORIDE 600 MG/300 ML (2 MG/ML) Rx only</p> <p>Store at 20 to 25°C (68 to 77°F) [See USP Controlled Room Temperature.]</p> <p>Distributed by Hospira, Inc., Lake Forest, IL 60045 USA</p> <p>MADE IN SINGAPORE</p> <p>LOT 00000000 EXP MM/YYYY QTY: 01</p> <p>(17)YYMMDD(10)00000000(30)01</p> <p>(01)00304094883106(21)000000000000</p> <p>FULL 0733 01-883-12-027</p>

Contact your local wholesaler with your updated forecast for this product.

Please contact your sales representative or your account executive for any other questions. For medical inquiries, please contact Pfizer Medical Information at 1-800-438-1985.

Thank you,

Angelika Piatek
Portfolio Director, Premix, Specialty Solutions, & Micronutrients
Pfizer Hospital US

