Click for <u>Full Prescribing Information</u> including BOXED WARNING, if applicable.

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



August 28, 2023

NDC and Labeling Change for Rocuronium Bromide Injection Multiple Dose Vial Presentations

Dear Valued Customer,

Pfizer Hospital is pleased to share the new NDC, with a labeling change, for **Rocuronium Bromide Injection 50 mg/5 mL (10 mg/mL) and 100 mg/10 mL (10 mg/ mL) Multiple Dose Vials** are now available at wholesalers and distributors (please note locational inventory may vary).

While there is a difference in NDC, label, and formulation, as detailed in the Transition Table below, there is no change to unit of sale size, unit of use price, or indication.

Please keep in mind that as we transition to the <u>new</u> NDCs both the <u>current</u> and <u>new</u> NDCs will be in the marketplace temporarily. However, until it is depleted, we request that you continue using the <u>current</u> NDCs when available.

TRANSITION TABLE

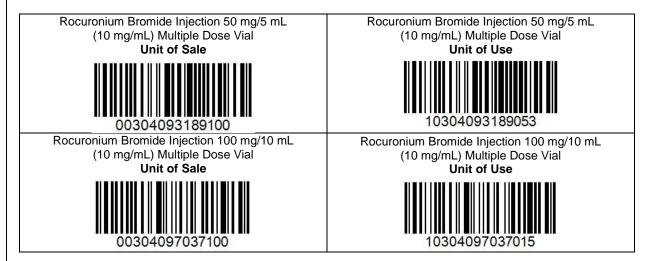
CURRENT NDC	NEW NDC INFORMATION				
Current Unit of Sale NDC Being Depleted	New Unit of Sale NDC Being Made Available	Ordering & Shipping Options	Product Description	Unit of Sale Pack Size	
00409-9558-05	00409-3189-10	Wholesaler and Distributor Only	Rocuronium Bromide Injection 50 mg/5 mL (10 mg/mL) Multiple Dose Vial	10	
00409-9558-10	09-9558-10 00409-7037-10 Wholesaler Distributor		Rocuronium Bromide Injection 100 mg/10 mL (10 mg/mL) Multiple Dose Vial	10	

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

WHOLESALER NUMBERS

NEW NDC Wholesaler Numbers					
NEW Unit of Sale NDC	NEW Unit of Use NDC	ABC	Cardinal	McKesson	Morris & Dickson
00409- 3189-10	00409- 3189-05	10281859	5861976	2838712	297317
00409- 7037-10	00409- 7037-01	10281944	5861984	2838720	297325

BARCODES – NEW NDC



PRODUCT INFORMATION FOR: Rocuronium Bromide Injection 50 mg/5 mL (10 mg/mL) Multiple Dose Vial

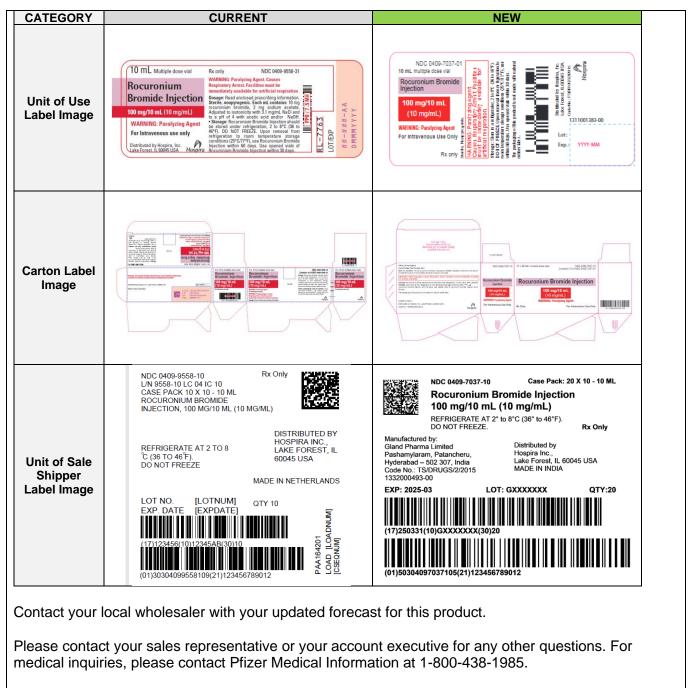
Rocuronium Bromide Injection 50 m			
Rocuronium Bromide Injection 50 mg/5 mL (10 mg/mL) Multiple Dose Vial			
00409-9558-05	00409-3189-10		
10 Multiple Dose Vials	10 Multiple Dose Vials		

CATEGORY	CURRENT		NEW	
	Common Name	Concentration	Common Name	Concentration
	Rocuronium Bromide	10 mg/mL	Rocuronium Bromide	10 mg/mL
	Sodium acetate trihydrate	1.2 mg/mL (as sodium Acetate Anhydrous)	Sodium acetate trihydrate	2.0 mg/mL
Formulation	Sodium Chloride	3.1 mg/mL	Sodium Chloride	3.1 mg/mL
	Acetic acid	q.s. for pH adjustment	Acetic acid	q.s. for pH adjustment
	Sodium hydroxide	q.s. for pH adjustment	Sodium hydroxide	q.s. for pH adjustment
	Water for Injection	q.s. to 1.0 mL	Water for Injection	q.s. to 1.0 mL
Unit of Use Vial Image	Song/Sml Bromide Inj. Song/Sml Bromide Inj. Song/Sml Bromide Inj. Song/Sml Bromide Inj. Song/Sml		NDC 0495-3180.5 NDC 0495-3180.5 Not more and the second	
Unit of Use Label Image	Bromide Injection 50 mg/5 mL (10 mg/mL) WARNING: Paralyzing Agest For Intravenous use only bromin para		NDC 0409-3189-05 5 mL multiple dose vial Rocurronium Bromide Injection 50 mg/5 mL (10 mg/mL) WARNING: Branybrighted Storage Store in a refigerato, 21 b 50 61 b or 1/b con FREEZE, 10 mg/store in refigerative indicate optimizer in 10 mg/mL) WARNING: Branybrighted 10 d or 0/m Con FREEZE, 10 mg/store in refigerative indicate optimizer in the opened vias within 30 disp. Che opened vi	
Carton Label Image	August and a second and a	50 mg/5 mL (10 mg/mL) Theory State of the second of the se	A constraint of the second sec	10 - Information and Information 10 - Information



PRODUCT INFORMATION FOR: Rocuronium Bromide Injection 100 mg/10 mL (10 mg/mL) Multiple Dose Vial

CATEGORY	CURRENT		NEW		
Product Description	Rocuronium Bromide Injection 100 mg/10 mL (10 mg/mL) Multiple Dose Vial				
Unit of Sale NDC	00409-9558-10		00409-7037-10		
Unit of Sale Size	10 Multiple Dose Vials		10 Multiple Dose Vials		
Formulation	Common Name	<u>% Composition or</u> Other Measure	Common Name	<u>% Composition or</u> Other Measure	
	Rocuronium Bromide	10 mg/mL	Rocuronium Bromide	10 mg/mL	
	Sodium acetate trihydrate	1.2 mg/mL (as sodium Acetate Anhydrous)	Sodium acetate trihydrate	2.0 mg/mL	
	Sodium Chloride	3.1 mg/mL	Sodium Chloride	3.1 mg/mL	
	Acetic acid	q.s. for pH adjustment	Acetic acid	q.s. for pH adjustment	
	Sodium hydroxide	q.s. for pH adjustment	Sodium hydroxide	q.s. for pH adjustment	
	Water for Injection	q.s. to 1.0 mL	Water for Injection	q.s. to 1.0 mL	
Unit of Use Vial Image	10 mL Multiple does vial Recurronium To my fait 10 mg/		NDCC 0409-318945 3 mL multiple dose wild Rocuronium Bromds Injection 50 mg/5 mL (10 mg/mL) Werkerschartung dost Ro only Turker		
	Yellow Cap with Yellow Ferrule		Yellow Cap with Aluminum Ferrule		



Thank you,

Jennifer Meek Portfolio Director, Anesthesia Pfizer Hospital U.S.



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