URGENT: VACCINE RECALL

MERCK

[30Jun2023]
Event ID: [3883]

PRODUCT	Trade Name: Strength:	**VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection (0.5 mL Prefilled Syringe)**
	NDA Holder:	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. (Merck)
	NDC Number:	NDC 0006-4329-01 (Syringe) NDC 0006-4329-03 (10X Carton) NDC 0006-4329-02 (1X Carton)
	Package Size:	10 Syringes in 1 Carton (W021510, W021512, W027250, W028846) and 1 Syringe in 1 Carton (W021637)
	Lot Number/Exp Date:	<table><tr><th>Lot Number</th><th>Expiration Date</th></tr><tr><td>W021510</td><td>08Oct2023</td></tr><tr><td>W021512</td><td>08Oct2023</td></tr><tr><td>W021637</td><td>08Oct2023</td></tr><tr><td>W027250</td><td>09Jul2024</td></tr><tr><td>W028846</td><td>21Nov2023</td></tr></table>
	Distribution:	Distribution by Merck occurred in the United States from 22Jul2022-06Jul2023
	Manufactured By:	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. West Point, PA 19486 U.S.A.

REASON	The Company has received reports of breakage at the syringe flange and/or hub that were identified when the syringe was inspected before administration, while the healthcare professional was securing the needle to the syringe, during vaccine administration or during post-administration (e.g., when activating a safety needle). The breakage resulted in a small number of injuries, including laceration and needle puncture.
ACTION	In order to ensure an effective recall and return process, it is important that you do the following: 1. Please examine your inventory and quarantine all VAXNEUVANCE™ vaccine cartons and glass syringes labeled as belonging to Lots W021510, W021512, W021637, W027250, W028846. • Please return the vaccine according to the procedure described below. • For Distributors and wholesalers, if you have further distributed material from these lots, please conduct a sub-recall and notify your customers of this product recall, as described on the next page. • For Healthcare Providers and Healthcare Systems, If you have further distributed

URGENT: VACCINE RECALL

MERCK

material from these lots, please notify the recipients of this product recall, as described on the next page.

2. Please complete the enclosed Business Reply Cards and the Packing Slips labeled "Non-VFC (Vaccines For Children) or Non-CDC Vaccine" and "CDC VFC (Vaccines for Children) and CDC Adult Vaccine," including the entry of number of cartons / syringes returned.

3. Please return a copy of the business reply cards, **even if you do not have any of the product subject to this recall**, so that we can be sure to account for all product distributed.

4. Return all of the product identified above and the Packing Slip using the prepaid Shipping Labels to:

Sedgwick, Inc.
Attn: Event ID 3883
2670 Executive Drive, Suite A
Indianapolis, IN 46241

Or Fax: 888-345-1438 / Email: merck3883@sedgwick.com

If you have both Non-VFC / Non-CDC and VFC / CDC vaccine to return, you may ship them together in the same shipping container as long as you have accounted for the syringes separately using the appropriate forms outlined above.

ACTION (continued)

For product that has been further distributed:

1. Please notify any customers or recipients of product to whom you distributed Lots W021510, W021512, W021637, W027250, W028846 of VAXNEUVANCE™ and request that they immediately examine their inventory and quarantine all product from these lots. Please include a copy of the following in the notification to customers:
   - the "Dear Customer Letter" (attached) and
   - this Notification of Vaccine Recall
2. Instruct the customers or recipients to contact Sedgwick, Inc. at: 888-275-0506 for product return instructions. Prepaid packing slips and business reply cards will be provided to all customers by Sedgwick, Inc.

OTHER INFORMATION

For questions about the recall process (including how to return the recalled product and reimbursement for returned product), please contact:
Sedgwick, Inc.: 888-275-0506

For questions about this recall or to report any adverse events, please contact:
Merck's National Service Center: 800-672-6372, Select Prompt #1, then Prompt #2.

URGENT: VACCINE RECALL

MERCK

	Monday to Friday 8:00 AM to 7:00 PM (EST) Through the use of the enclosed Packing Slip and pre-paid UPS Shipping Label to Sedgwick, Inc., Merck will pay transportation charges for product returned as a result of this recall. Please include your customer name, address, name of your wholesaler or distributor from whom you purchased this product (if appropriate) and Merck account number (if appropriate) with each shipment. Direct Merck Customers: Reimbursement for product returned under this recall will be issued as credit to customers that have an account with Merck, at a price that is appropriate for the returning customer. Non-Direct Customers (via wholesalers / distributors): Reimbursement for product returned under this recall will be issued as a credit to the distributor, for that provider, at a price that is appropriate for that returning customer. CDC Contract Doses: Reimbursement for product returned under this recall will be issued as per the Terms & Conditions of the CDC Contract. This voluntary recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience caused by this action.

Non-VFC (Vaccines For Children) or Non-CDC Adult Vaccine

Use other BRC for VFC or CDC Adult Vaccine

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection Lots (For Non-VFC (Vaccines for Children) or Non-CDC Adult Vaccine)

NDC #	PACKAGE SIZE	LOT #	EXP. DATE	Number of Full 10x Cartons or 1X Carton to be Returned	Number of pre-filled syringes from Partial Cartons to be returned
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W021510	08Oct2023		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W027250	09Jul2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W021512	08Oct2023		
0006-4329-01 (Syringe) **0006-4329-02 (Carton)**	1 Glass Syringe, in 1X Carton	W021637	08Oct2023		N/A
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W028846	21Nov2023		

BUSINESS REPLY CARD

Merck Sharp & Dohme LLC

VAXNEUVANCE™
19Jul2023

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, **even if you do not have the recalled product.** Thank you.

Signature _____ Title _____

Name _____ Phone _____

VAXNEUVANCE™ (Pneumococcal 15 valent-Conjugate Vaccine) Suspension for Intramuscular Injection (For Non-VFC (Vaccines for Children) or Non-CDC Adult Vaccine)

NDC #	PACKAGE SIZE	LOT #	EXP. DATE	Number of Full 10x Cartons or 1X Carton to be Returned	Number of pre-filled syringes from Partial Cartons to be returned
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W021510	08Oct2023		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W027250	09Jul2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W021512	08Oct2023		
0006-4329-01 (Syringe) **0006-4329-02 (Carton)**	1 Glass Syringe, in 1X Carton	W021637	08Oct2023		N/A
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W028846	21Nov2023		

PACKING SLIP

Merck Sharp & Dohme LLC

VAXNEUVANCE™
19Jul2023

The following information is required to assure proper crediting:

Debit Memo (optional): _____

Firm Name: _____

Address: _____

_____

Merck Account Number: _____

If ordered through a wholesaler or distributor, please indicate wholesaler or distributor name in space provided.

Wholesaler/Distributor Name:_____

CDC VFC (Vaccines for Children) and CDC Adult Vaccine

Use other BRC for Non-VFC or Non-CDC Adult Vaccine

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine)
Suspension for Intramuscular Injection (For VFC (Vaccines for Children) or CDC Adult Vaccine)

NDC #	PACKAGE SIZE	LOT #	EXP. DATE	Number of Full 10x Cartons or 1X Carton to be Returned	Number of pre-filled syringes from Partial Cartons to be returned
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W021510	08Oct2023		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W027250	09Jul2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W021512	08Oct2023		
0006-4329-01 (Syringe) **0006-4329-02 (Carton)**	1 Glass Syringe, in 1X Carton	W021637	08Oct2023		N/A
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W028846	21Nov2023		

BUSINESS REPLY CARD

Merck Sharp & Dohme LLC

VAXNEUVANCE™
19Jul2023

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, **even if you do not have the recalled product.** Thank you.

Signature _____ Title _____

Name _____ Phone _____

CDC VFC (Vaccines for Children) and CDC Adult Vaccine

Use other BRC for Non-VFC or Non-CDC Adult Vaccine

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine)
Suspension for Intramuscular Injection (For VFC (Vaccines for Children) or CDC Adult Vaccine)

NDC #	PACKAGE SIZE	LOT #	EXP. DATE	Number of Full 10x Cartons or 1X Carton to be Returned	Number of pre-filled syringes from Partial Cartons to be returned
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W021510	08Oct2023		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W027250	09Jul2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W021512	08Oct2023		
0006-4329-01 (Syringe) **0006-4329-02 (Carton)**	1 Glass Syringe, in 1X Carton	W021637	08Oct2023		N/A
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W028846	21Nov2023		

PACKING SLIP CARD

Merck Sharp & Dohme LLC

VAXNEUVANCE™
19Jul2023

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, **even if you do not have the recalled product.** Thank you.

Signature _____ Title _____

Name _____ Phone _____

MERCK

URGENT: VACCINE RECALL

July 2023

Dear Customer:

This is to inform you of a voluntary product recall of:

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine)
Suspension for Intramuscular Injection Lots W021510, W021512, W021637
W027250, W028846

See enclosed product label for ease in identifying the product at the wholesaler, distributor, or health care provider levels.

Merck has initiated a voluntary recall of VAXNEUVANCE™ Lots W021510, W021512, W021637, W027250, W028846 in the US market. The Company has received reports of breakage at the syringe flange and/or hub that could be identified when the syringe was inspected before administration, while the healthcare professional was securing the needle to the syringe, during vaccine administration or during post-administration (e.g., when activating a safety needle). The breakage resulted in a small number of injuries, including laceration and needle puncture.

Our Company's investigation to date has determined the breakage to result from a step in the syringe supplier manufacturing process that causes weakness in the glass and a subsequent force that results in glass breakage. Actions have been implemented at the syringe manufacturer to improve processes to help prevent these defects from recurring in future lots. VAXNEUVANCE™ syringes from these five lots under recall have exhibited higher complaint rates for glass breakage at the hub and flange.

Accordingly, Merck recommends that if you have VAXNEUVANCE™ from any of the recalled lots at your facility, you immediately quarantine and discontinue use of these doses and return all these pre-filled syringes in accordance with the attached recall notification. This product was distributed between 22Jul2022 and 06Jul2023.

Immediately examine your inventory and quarantine product subject to this recall. In addition, if you have further distributed this product, please identify your customers and notify them at once of this product recall. Enclosed is a letter you should use in notifying your customers.

This recall should be carried out to the user level, including healthcare professionals and administering institutions. Your assistance is appreciated and necessary to prevent further potential injuries.

Please complete the enclosed Business Reply Cards and the Packing Slips labeled "Non-VFC (Vaccines For Children) or Non-CDC Vaccine" and "CDC VFC (Vaccines for

MERCK

Children) and CDC Adult Vaccine," including the entry of number of cartons / syringes returned as soon as possible.

This recall is being made with the knowledge of the United States Food and Drug Administration.

Martha Bomar

Martha Bomar
Associate Vice President, West Point Quality Operations
770 Sumneytown Pike, WP36M-5
West Point, PA 19486
Phone: +1 (215) 652-4654
Email: martha.bomar@merck.com

Confidential

MERCK

URGENT: VACCINE RECALL

July 2023

Dear Customer:

This is to inform you of a voluntary product recall of:

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine)
Suspension for Intramuscular Injection Lots W021510, W021512, W021637, W027250, W028846

Merck has initiated a voluntary recall of VAXNEUVANCE™ Lots W021510, W021512, W021637, W027250, W028846 in the US market. The Company has received reports of breakage at the syringe flange and/or hub that were identified when the syringe was inspected before administration, while the healthcare professional was securing the needle to the syringe, during vaccine administration or during post-administration (e.g., when activating a safety needle). The breakage resulted in a small number of injuries reported, including laceration and needle puncture.

Our Company's investigation to date has determined the breakage to result from a step in the syringe supplier manufacturing process that causes weakness in the glass and a subsequent force that results in glass breakage. Actions have been implemented at the syringe manufacturer to improve processes to prevent these defects from recurring in future batches. VAXNEUVANCE™ syringes from these five lots under recall have exhibited higher complaint rates for glass breakage at the hub and/or flange.

Accordingly, Merck recommends that if you have the affected lots at your facility, immediately quarantine and discontinue distributing or dispensing any syringes and return all syringes in accordance with the attached recall notification. A separate healthcare professional letter will be issued to providers with recommendations for handling of syringes remaining in distribution.

For questions about this recall or to report any adverse events following vaccination, please contact:

- Merck National Service Center: 800-672-6372 Select Prompt #1 then Prompt #2. (Monday to Friday 8:00 AM to 7:00 PM EST)

This voluntary recall is being conducted with the knowledge of the United States Food and Drug Administration.

We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience caused by this action.

Anne E. de Papp MD

Anne E. de Papp, MD
Vice President & Head US Medical Affairs
Global Medical & Scientific Affairs
Merck Research Labs
Merck Sharp & Dohme LLC