URGENT: VACCINE RECALL

MERCK

January 2024
Event ID: 8681

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 0006-4329-02 (1X Carton) NDC 0006-4329-03 (10X Carton)
	Package Size:	**1 Syringe in 1 Carton:** W037992 **10 Syringes in 1 Carton:** W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735
	Lot Number/Exp Date:	See table below
	Distribution:	Distribution by Merck occurred in the United States from 16-Nov-2022 through 28-Jul-2023
	Manufactured By:	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc. West Point, PA 19486 U.S.A.

Lot Number	Expiration Date
W037992	10Dec2024
W027275	09Jul2024
W036242	01Oct2024
W039033	01Oct2024
X004289	10Dec2024
X005583	10Dec2024
X011328	01Jan2025
X011332	01Jan2025
X012044	10Jan2025
X011735	10Jan2025

REASON	Merck 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. Corrective Action and Preventative Actions (CAPA) have been implemented at the syringe manufacturer to improve processes to help prevent these defects from recurring in future lots and Merck informed Health Care Providers of the glass breakage issue for syringe breakage and provided guidance for handling and administration to further mitigate the risk of injury for the remaining material on the market until post-CAPA material is supplied. Merck has accelerated the supply of post-CAPA material to the U.S. market and has established a stable supply of this

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	post-CAPA VAXNEUVANCE™ material to U.S. customer. Therefore, the recall is being expanded given the stable supply of post-CAPA material at this time.
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 W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735.** • Please return the vaccine according to the procedure described below. • If you have further distributed material from these lots, please conduct a sub-recall and notify your customers of this product recall, as described below. 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 8681 2670 Executive Drive, Suite A Indianapolis, IN 46241 Or Fax: **877-546-9063**/ Email: merck8681@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)	<u>For product that has been further distributed:</u> 1. Please notify any customers or recipients of product to whom you distributed **Lots W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735 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

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	2. Instruct the customers or recipients to contact Sedgwick, Inc. at: 877-650-9404 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 processing of returned product), please contact: Sedgwick, Inc.: (877) 650-9404 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. 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, and Merck account number (if appropriate) with each shipment. <u>Direct Merck Customers:</u> 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. <u>Non-Direct Customers (via wholesalers / distributors):</u> 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. <u>CDC Contract Doses:</u> 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.

MERCK

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January 2024

Dear Customer,

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

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine)
Suspension for Intramuscular Injection
Lots W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735

See enclosed product label for ease in identifying the product at the wholesale/CDC or user levels.

We previously contacted you regarding the voluntary product recall of certain lots of VAXNEUVANCE™. This is to inform you that Merck has expanded the voluntary recall for VAXNEUVANCE™ Lots **W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735** in the US market to **the user level.** 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. Corrective Action and Preventative Actions (CAPA) have been implemented at the syringe manufacturer to improve processes to help prevent these defects from recurring in future lots. VAXNEUVANCE™ syringes from ten Lots (**W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735)** under the scope of this recall have the potential for these defects to be present. Merck has accelerated the supply of post-CAPA material to the U.S. market and has established a stable supply of this post-CAPA VAXNEUVANCE™ material to U.S. customers. Therefore, the recall is being expanded given the stable supply of post-CAPA material at this time.

Accordingly, Merck recommends that if you have VAXNEUVANCE™ from Lots **W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735** or 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 16-Nov-2022 through 28-Jul-2023.

MERCK

Immediately examine your inventory and quarantine product subject to this recall.

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 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

MERCK

URGENT: VACCINE RECALL

January 3, 2024

Dear Provider,

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

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection Lots W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735

We previously contacted you regarding the voluntary product recall of certain lots of VAXNEUVANCE™. This is to inform you that Merck has expanded the voluntary recall for VAXNEUVANCE™ lots **W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735** in the US market to the user level. 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. Corrective Action and Preventative Actions (CAPA) have been implemented at the syringe manufacturer to improve processes to prevent these defects from recurring in future batches. VAXNEUVANCE™ syringes from ten Lots (W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735) under the scope of this recall have the potential for these defects to be present. Merck has accelerated the supply of post-CAPA material to the U.S. market and has established a stable supply of this post-CAPA VAXNEUVANCE™ material to U.S. customers. Therefore, the recall is being expanded given the stable supply of post-CAPA material at this time.

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.

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)

MERCK

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

BUSINESS REPLY CARD
For Non-VFC (Vaccines for Children) or Non-CDC Adult Vaccine

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection

(Lots W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735)

NDC 0006-4329-01 (Syringe)
NDC 0006-4329-02 (1X Carton)
NDC 0006-4329-03 (10X Carton)

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the Customer Recall Notification Letter.

□ **(For Warehouse / Distribution centers only)** I have identified and notified my customers that were shipped or may have been shipped this product by - specify date and method of notification:

_____

Please check the appropriate box(es) to describe your business
□ wholesaler/distributor
□ hospital/medical facility
□ hospital pharmacy
□ clinic
□ retail pharmacy
□ other: _____

□ I have checked my stock and have quarantined all inventory, listed below.

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection

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) **0006-4329-02 (Carton)**	1 Glass Syringe, in 1X Carton	W037992	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W027275	09Jul2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W036242	01Oct2024		

Merck Sharp & Dohme LLC

VAXNEUVANCE™
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0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W039033	01Oct2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X004289	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X005583	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011328	01Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011332	01Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X012044	10Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011735	10Jan2025		

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

Firm Name: _____ Address: _____

Name: _____ Phone: _____

PACKING SLIP

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

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine)
Suspension for Intramuscular Injection

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) **0006-4329-02 (Carton)**	1 Glass Syringe, in 1X Carton	W037992	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W027275	09Jul2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W036242	01Oct2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W039033	01Oct2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X004289	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X005583	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011328	01Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011332	01Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X012044	10Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011735	10Jan2025		

Merck Sharp & Dohme LLC

VAXNEUVANCE™
XXJAN2024

Sedgwick Event ID: 8681

Firm Name: _____ Address: _____

Name: _____ Phone: _____

Debit Memo: (if applicable) _____ Merck Account Number: (if applicable) _____

DEA Number: _____ 340B ID Number: (if applicable) _____

HIN Number: (if applicable) _____

If you ordered through a wholesaler, distributor, or CDC, please indicate the name of the wholesaler or distributor below.

Wholesaler/Distributor Name:_____

BUSINESS REPLY CARD
For VFC (Vaccines for Children) or CDC Adult Vaccine

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection

(Lots W037992, W027275, W036242, W039033, X004289, X005583, X011328, X011332, X012044, X011735)

NDC 0006-4329-01 (Syringe)
NDC 0006-4329-02 (1X Carton)
NDC 0006-4329-03 (10X Carton)

Please check ALL appropriate boxes.

□ I have read and understand the recall instructions provided in the Customer Recall Notification Letter.

□ **(For Warehouse / Distribution centers only)** I have identified and notified my customers that were shipped or may have been shipped this product by - specify date and method of notification:

_____

Please check the appropriate box(es) to describe your business
□ wholesaler/distributor
□ hospital/medical facility
□ hospital pharmacy
□ clinic
□ retail pharmacy
□ other: _____

□ I have checked my stock and have quarantined all inventory, listed below.

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection

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) **0006-4329-02 (Carton)**	1 Glass Syringe, in 1X Carton	W037992	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W027275	09Jul2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W036242	01Oct2024		

Merck Sharp & Dohme LLC

VAXNEUVANCE™
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0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W039033	01Oct2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X004289	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X005583	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011328	01Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011332	01Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X012044	10Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011735	10Jan2025		

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

Firm Name: _____ Address: _____

Name: _____ Phone: _____

PACKING SLIP

For VFC (Vaccines for Children) or CDC Adult Vaccine

VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection

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) **0006-4329-02 (Carton)**	1 Glass Syringe, in 1X Carton	W037992	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W027275	09Jul2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W036242	01Oct2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	W039033	01Oct2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X004289	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X005583	10Dec2024		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011328	01Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011332	01Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X012044	10Jan2025		
0006-4329-01 (Syringe) **0006-4329-03 (Carton)**	10 Glass Syringes, in 1 Carton	X011735	10Jan2025		

Merck Sharp & Dohme LLC

VAXNEUVANCE™
XXJAN2024

Sedgwick Event ID:
8681

Firm Name: _____ Address: _____

Name: _____ Phone: _____

Debit Memo: (if applicable) _____ Merck Account Number: (if applicable) _____

DEA Number: _____ 340B ID Number: (if applicable) _____

HIN Number: (if applicable) _____

If you ordered through a wholesaler, distributor, or CDC, please indicate the name of the wholesaler or distributor below.

Wholesaler/Distributor Name:_____