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: 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 processing of returned product), please contact: Sedgwick, Inc.: (866) 817-2863 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.