

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Merck has received reports of breakage of **VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection (0.5 mL Prefilled Syringe)** 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 time.

PRODUCT NAME: VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Suspension for Intramuscular Injection (0.5 mL Prefilled Syringe)

NDC NUMBERS:

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

LOT NUMBERS:

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

X011735

10Jan2025

DISTRIBUTION DATES: 11/16/2022 - 7/28/2023