

URGENT: Notification of VACCINE RECALL



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October 19, 2020

Dear Customer:

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

**PNEUMOVAX[®]23 (Pneumococcal Vaccine Polyvalent),
Lots S036495 and S027047**

Merck Sharp & Dohme Corp, a subsidiary of Merck & Co., Inc. ("Merck"), has initiated this voluntary recall because a limited number of units of PNEUMOVAX[®]23 prefilled syringes belonging to Lot S036495 and PNEUMOVAX[®]23 vials belonging to Lot S027047 were stored at temperatures outside their respective temperature specifications during their shipment, by a third-party delivery service, to the McKesson Medical Surgical Inc. ("McKesson") facility in Chino, California, prior to further shipment to customers of McKesson.

This recall only affects PNEUMOVAX[®]23 prefilled syringes or vials that:

- belong to Lot S036495 (prefilled syringes) or Lot S027047 (vials); and
- were shipped from the McKesson facility in Chino, California; and
- were received and/or administered by customers of McKesson on or after August 12, 2020.

PNEUMOVAX[®]23 is a temperature-sensitive vaccine and exposure to temperatures above the recommended storage conditions of 2-8°C (36-46°F) may reduce the potency of the vaccine and potentially impact vaccine effectiveness. Available stability data suggest that there will be little to no effect on the appearance of the vaccine or on the integrity and performance of the syringe or vial as a result of exposure to temperatures above the recommended storage conditions.

Merck recommends that healthcare providers (HCPs) receiving this notice immediately discontinue use of PNEUMOVAX[®]23 prefilled syringes belonging to Lot S036495 and PNEUMOVAX[®]23 vials belonging Lot S027047. Merck also suggests that HCPs receiving this notice review the records of individuals who were vaccinated with PNEUMOVAX[®]23 on or after August 12, 2020 to determine if any individuals received a dose of PNEUMOVAX[®]23 from either affected lot. In the event that a dose from either of the affected lots was administered, another dose of PNEUMOVAX[®]23 is advised at the earliest opportunity.

The HCP should consider the individual's clinical need and discuss with the individual the benefit-risk of vaccination.

In order to ensure an effective recall and return process, please examine your inventory and quarantine all remaining units of PNEUMOVAX[®]23 prefilled syringes belonging to Lot S036495 and PNEUMOVAX[®]23 vials belonging to Lot S027047. Once quarantined, product should be returned according to the following procedure:

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- Please complete and return the enclosed postage-paid business reply card(s) and packing slip(s) as soon as possible. Please be sure to indicate the number of units from the recalled lot that you have returned.
- Please complete and return a copy of the business reply card(s) and packing slip(s) even if you do not have in your inventory any remaining units of the affected lot, so that we can be sure to account for all units distributed or administered.
- Using the prepaid shipping label(s), please return the packing slip(s) and all units belonging to the affected lot in your inventory to:

Stericycle, Inc.
Attn: Event 5707
2670 Executive Drive, Suite A
Indianapolis, IN 46241

If you require additional prepaid shipping labels, packing slips or business reply cards, please contact Stericycle, Inc. at (888) 566-2512.

PNEUMOVAX[®]23 Lot S036495 and Lot S027047 are the only lots impacted this recall. The units from the subject lot were further distributed by McKesson solely within the United States (California, Hawaii, and Nevada). This recall will not impact the supply of PNEUMOVAX[®]23. There is adequate inventory to replace recalled product at this time.

For questions about the recall process, including how to return the units belonging to the affected lot, please contact:

- Stericycle, Inc. at (888) 566-2512
- If you have any other questions about this recall or wish to report any adverse events following vaccination, please contact:
 - the Merck National Service Center at (800) 672-6372 (Monday to Friday, 8:00 a.m. to 7:00 p.m. (EST)). Select Prompt #1 then Prompt #2.

In addition, adverse events or quality problems experienced with the use of this product may be reported to the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS) by calling (800) 822-7967 or online at www.vaers.hhs.gov.

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INDICATION AND USAGE

PNEUMOVAX 23 is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F).

PNEUMOVAX 23 is approved for use in persons 50 years of age or older and persons aged ≥ 2 years who are at increased risk for pneumococcal disease.

PNEUMOVAX 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

SELECT SAFETY INFORMATION

Do not administer PNEUMOVAX 23 to individuals with a history of a hypersensitivity reaction to any component of the vaccine.

Defer vaccination with PNEUMOVAX 23 in persons with moderate or severe acute illness.

Use caution and appropriate care in administering PNEUMOVAX 23 to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

Available human data from clinical trials of PNEUMOVAX 23 in pregnancy have not established the presence or absence of a vaccine-associated risk.

Since elderly individuals may not tolerate medical interventions as well as younger individuals, a higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out.

Persons who are immunocompromised, including persons receiving immunosuppressive therapy, may have a diminished immune response to PNEUMOVAX 23.

PNEUMOVAX 23 may not be effective in preventing pneumococcal meningitis in patients who have chronic cerebrospinal fluid (CSF) leakage resulting from congenital lesions, skull fractures, or neurosurgical procedures.

The most common adverse reactions, reported in $>10\%$ of subjects vaccinated with PNEUMOVAX 23 for the first time in a clinical trial, were: injection-site pain/soreness/tenderness, injection-site swelling/induration, headache, injection-site erythema, asthenia and fatigue, and myalgia.

For subjects aged 65 years or older in a clinical study, systemic adverse reactions which were determined by the investigator to be vaccine-related were higher following revaccination than following initial vaccination.

Vaccination with may not offer 100% protection from pneumococcal infection.

Before administering PNEUMOVAX®23, please read the [Prescribing Information](#). The [Patient Information](#) also is available. The Prescribing Information and Patient Information also can be obtained from the Merck National Service Center or at www.merckvaccines.com.

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Customers will be reimbursed for the units impacted by the recall of PNEUMOVAX[®]23 that are returned as described above. Customers with questions about units that have been administered to patients should call the Merck National Service Center at 800-672-6372, select Prompt #1 then Prompt #2 (Monday to Friday 8:00 AM to 7:00 PM EST).

This 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.

Sincerely,

A handwritten signature in blue ink, appearing to read "R. Haupt", with a long horizontal line extending to the right.

Richard M. Haupt, MD, MPH
Vice President and Head, Vaccines & Infectious Diseases
Global Medical & Scientific Affairs
Merck Research Labs
Merck Sharp & Dohme Corp.