Vaxneuvance®
Pneumococcal 15-valent
Conjugate Vaccine

Discover the importance of IPD protection, including in the first year of life[1-4]

VAXNEUVANCE delivered a robust immune response against 15 serotypes postdose 3 and postdose 4 vs PCV13

VAXNEUVANCE is administered as a 4-dose series at 2, 4, 6, and 12 through 15 months of age.

IPD, invasive pneumococcal disease; PCV13, 13-valent pneumococcal conjugate vaccine.

Indications and Usage

VAXNEUVANCE is indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older.

Select Safety Information

Do not administer VAXNEUVANCE to individuals with a severe allergic reaction (eg, anaphylaxis) to any component of VAXNEUVANCE or to diphtheria toxoid.

Some individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to VAXNEUVANCE.

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Vaccination of premature infants should be based on the infant's medical status and the potential benefits and possible risks.

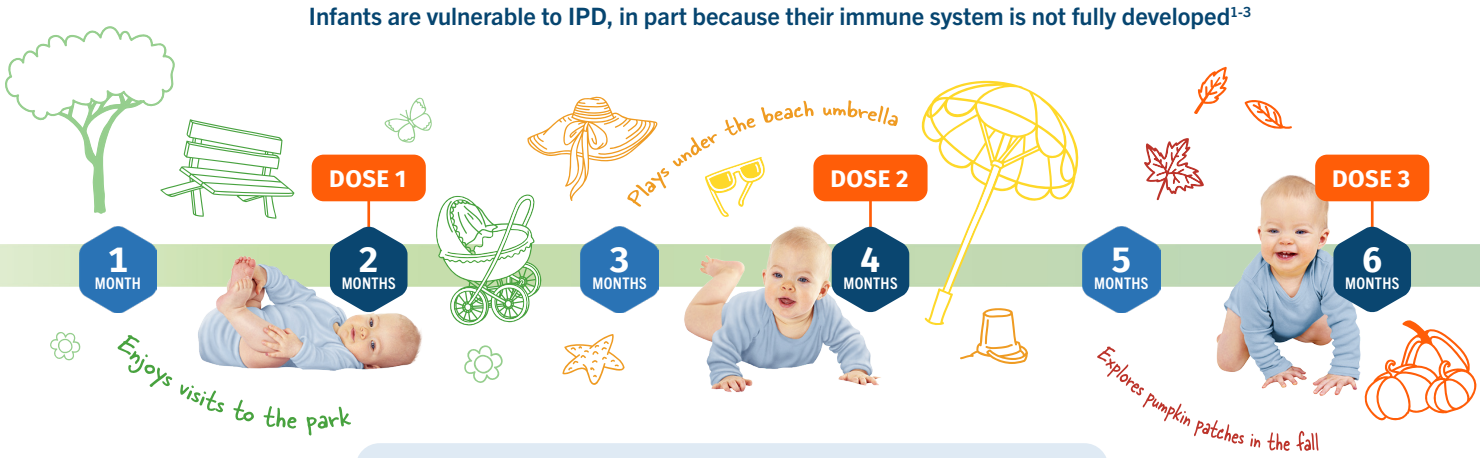
The most commonly reported solicited adverse reactions in children vaccinated at 2, 4, 6, and 12 through 15 months of age, provided as a range across the 4-dose series, were: irritability (57.3% to 63.4%), somnolence (24.2% to 47.5%), injection-site pain (25.9% to 40.3%), fever ≥38.0°C (13.3% to 20.4%), decreased appetite (14.1% to 19.0%), injection-site induration (13.2% to 15.4%), injection-site erythema (13.7% to 21.4%), and injection-site swelling (11.3% to 13.4%).

The most commonly reported solicited adverse reactions in children 2 through 17 years of age vaccinated with a single dose were: injection-site pain (54.8%), myalgia (23.7%), injection-site swelling (20.9%), injection-site erythema (19.2%), fatigue (15.8%), headache (11.9%), and injection-site induration (6.8%).

Vaccination with VAXNEUVANCE may not protect all vaccine recipients.

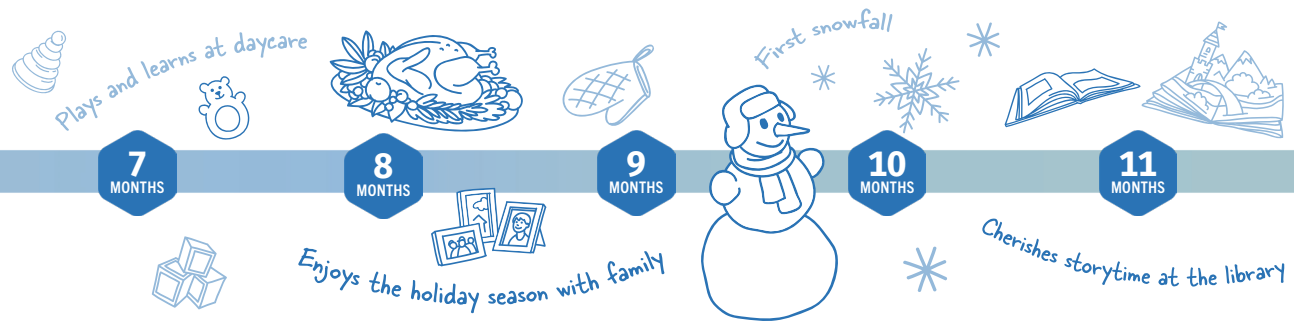
In a pooled analysis from 2018–2021, children were at the highest risk of pediatric IPD during the first year of life[1,a]

Infants are vulnerable to IPD, in part because their immune system is not fully developed[1-3]



The CDC recommends PCVs as a 4-dose series given at months 2, 4, and 6 with a booster dose given at 12–15 months.[5]

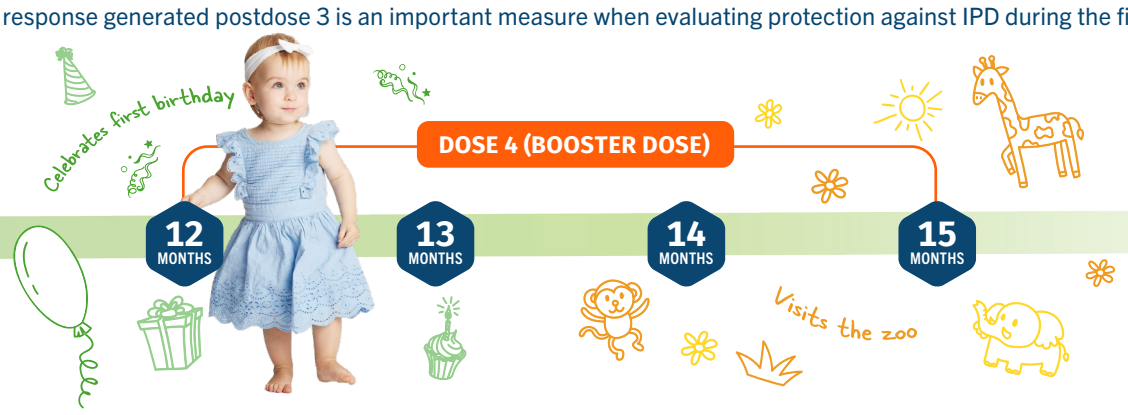
Children wait 6–9 months after the 3rd dose of a PCV series until they're able to receive the 4th dose[5]



Despite CDC's recommendation as a 4-dose series, about **1 in 6** toddlers received 3 or fewer of the 4 recommended PCV doses by 2 years of age.[5,6,b]

When it comes to IPD protection, immunogenicity matters through the first year of life and beyond[4,7-10]

The immune response generated postdose 3 is an important measure when evaluating protection against IPD during the first year of life.[5,9,10]



Achieve robust immune responses for the first year of life and beyond

[a]The CDC's ABC surveillance areas for *S. pneumoniae* included 10 states from 2018–2021, with >34 million persons per year; the rates of IPD per 100k babies were 10.2 at <1 year, 8.4 at 1 year, and 3.3 at 2 to 4 years of age.[1]

[b]NIS-Child, a random digit-dialed telephone survey of parents/guardians of children aged 19–35 months that the CDC used to estimate the vaccination coverage with ACIP-recommended vaccines in the US among children born in 2019 and 2020.[6]

ABC, Active Bacterial Core; ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention; IPD, invasive pneumococcal disease; NIS - Child, National Immunization Survey - Child; PCV, pneumococcal conjugate vaccine.

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(Select Safety Information continues on next page)

VAXNEUVANCE is administered as a 4-dose series at 2, 4, 6, and 12 through 15 months of age.

VAXNEUVANCE helps protect against pediatric IPD during the first year of life and beyond

VAXNEUVANCE delivered a robust immune response against 15 serotypes postdose 3 IgG response rates and postdose 4 GMC ratios, including[a]:

- Comparable immune responses for **12 shared serotypes** found in PCV13
- Superior immune responses for shared **Serotype 3** vs PCV13[b,c]
- Superior immune responses for **unique Serotypes 22F and 33F**—not covered by PCV13[11]

Randomized controlled trials assessing the clinical efficacy of VAXNEUVANCE compared to PCV13 have not been conducted.

No randomized controlled clinical trials have been conducted between PCV20 and VAXNEUVANCE in pediatric patients.[12]

GMC Ratios Postdose 3[a]

VAXNEUVANCE delivered comparable immune responses for 12 of the 13 shared serotypes found in PCV13. Shared serotype 6A was just below the noninferiority criteria by a small margin, with the lower bound of the 2-sided 95% CI for the GMC ratio being 0.48 vs >0.5.

Study Design

Double-blind, active-comparator-controlled study evaluating VAXNEUVANCE as a 4-dose series in healthy infants (N=1720) randomized to receive either VAXNEUVANCE or PCV13.

[a]Measurements were taken 30 days postdose specified.
[b]Postdose 3 IgG response rate percentage point difference vs PCV13, 19.1 (95% CI: 14.4, 24.0).
[c]Postdose 4 IgG GMC ratio vs PCV13, 1.43 (95% CI: 1.30, 1.57).

CI, confidence interval; GMC, geometric mean concentration (mcg/mL); IgG, Immunoglobulin G; IPD, invasive pneumococcal disease; PCV13, 13-valent pneumococcal conjugate vaccine; PCV20, 20-valent pneumococcal conjugate vaccine.

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Select Safety Information *(continued)*

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Before administering VAXNEUVANCE, please read the accompanying Prescribing Information. The Patient Information also is available. For additional copies of the Prescribing Information, please call 800-672-6372, visit MerckVaccines.com®, or contact your local Merck representative.

References: 1. Data available on request from Merck & Co., Inc., Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package US-PVC-01698. **2.** Moraes-Pinto MI, Suano-Souza F, Aranda CS. Immune system: development and acquisition of immunological competence. *J Pediatr (Rio J)*. 2021;97(S1):S59-S66. doi:10.1016/j.jped.2020.10.006 **3.** Wodi AP, Morelli V. *Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book)*. 14th edition. Chapter 1: Principles of vaccination. Centers for Disease Control and Prevention. Last reviewed August 18, 2021. Accessed January 26, 2024. https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/prinvac.pdf **4.** Gierke R, Wodi P, Kobayashi M. *Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book)*. 14th edition. Chapter 17: Pneumococcal disease. Centers for Disease Control and Prevention. Last reviewed August 18, 2021. Accessed April 10, 2024. https://www.cdc.gov/vaccines/pubs/pinkbook/pneumo.html **5.** Recommended child and adolescent immunization schedule for ages 18 years or younger, United States, 2024. Centers for Disease Control and Prevention (CDC). Updated November 16, 2023. Accessed November 16, 2023. https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf **6.** Hill HA, Yankey D, Elam-Evans LD, Chen M, Singleton JA. Vaccination coverage by age 24 months among children born in 2019 and 2020 — National Immunization Survey-Child, United States, 2020–2022. *MMWR Morb Mortal Wkly Rep.* 2023;72:(44)1190–1196. doi:10.15585/mmwr.mm7244a3 **7.** World Health Organization. Pneumococcal conjugate vaccines in infants and children under 5 years of age: WHO position paper - February 2019. *Weekly Epidemiological Record*. 2019;94(8):85-104. **8.** Gruber MF, Marshall VB. Regulation and testing of vaccines in the US. In: Orenstein WA, Offit PA, Edwards KM, Plotkin SA, eds. *Plotkin's Vaccines*. 8th ed. Elsevier; 2022:1640-1659.e2 **9.** World Health Organization. Recommendations to assure the quality, safety and efficacy of pneumococcal conjugate vaccines, Annex 3, TRS No 977. Last reviewed October 19, 2013. Accessed January 26, 2024. https://www.who.int/publications/m/item/pneumococcal-conjugate-vaccines-annex3-trs-977 **10.** Guidelines on clinical evaluation of vaccines: regulatory expectations. WHO Technical Report Series 1004, Annex 9, 2017. World Health Organization. Last reviewed October 21, 2020. Accessed July 18, 2023. https://www.who.int/publications/m/item/WHO-TRS-1004-web-annex-9 **11.** Prevnar 13. Prescribing Information. Pfizer, Inc.; 2019. **12.** Prevnar 20. Prescribing Information. Pfizer, Inc.; 2023.

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