Merck & Co., Inc.
351 N. Sumneytown Pike UG2B-01
North Wales, PA 19454

July 2022

Dear Health Care Professional,

Starting in October 2021, Merck provided VAXNEUVANCE™ (Pneumococcal 15-Valent Conjugate Vaccine) in both single-dose and 10-pack cartons of prefilled single-dose *Luer Lok* syringes (NDC 0006-4329-02 and NDC 0006-4329-03) with language on the product box reading "For use in individuals 18 years of age and older."

With the United States Food and Drug Administration (FDA) approval of VAXNEUVANCE for pediatric use on June 17, 2022, Merck will be removing the statement "For use in individuals 18 years of age and older" from newly manufactured boxes. In the interim, product in its original packaging can be used in appropriate infants and children. You may continue to purchase the single-dose or 10-pack cartons of prefilled single-dose *Luer Lok* syringes directly from Merck, as well as through wholesalers and physician distributors.

VAXNEUVANCE is supplied in the same 0.5 mL syringe for all approved age ranges.

Dosage and Administration

For intramuscular injection only. Each dose of VAXNEUVANCE is 0.5 mL.

Hold the prefilled syringe horizontally and shake vigorously immediately prior to use to obtain an opalescent suspension. Do not use the vaccine if it cannot be resuspended. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if particulate matter or discoloration is observed.

Administer as a 4-dose series at 2, 4, 6, and 12 through 15 months of age. Administer as a single dose in children and adolescents 2 through 17 years of age who did not receive a 4-dose series.

Administer VAXNEUVANCE as a single dose in adults 18 years of age and older.

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.

Appropriate medical treatment to manage allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of VAXNEUVANCE.

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.

(*Select Safety Information continues on next page*)

Select Safety Information (*continued*)

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%).

The most commonly reported solicited adverse reactions in individuals 18 through 49 years of age were: injection-site pain (75.8%), fatigue (34.3%), myalgia (28.8%), headache (26.5%), injection-site swelling (21.7%), injection-site erythema (15.1%), and arthralgia (12.7%).

The most commonly reported solicited adverse reactions in individuals 50 years of age and older were: injection-site pain (66.8%), myalgia (26.9%), fatigue (21.5%), headache (18.9%), injection-site swelling (15.4%), injection-site erythema (10.9%), and arthralgia (7.7%).

In studies of infants and children who received a 4-dose series of VAXNEUVANCE, injection-site urticaria within 14 days following each dose of VAXNEUVANCE occurred in up to 0.6% of children. Serious adverse events up to 6 months following vaccination with the 4-dose series were reported by 9.6% of VAXNEUVANCE recipients and by 8.9% of PCV13 recipients. Participants in these studies may have received either US-licensed or non-US licensed concomitant vaccines according to the local recommended schedule.

Up to 30 days following completion of Doses 1 through 3, serious adverse events were reported by 4.8% of VAXNEUVANCE recipients and by 5.0% of PCV13 recipients. An adverse reaction of febrile seizure was reported in a 9-week-old female one day after receiving VAXNEUVANCE (Dose 1) and recommended infant vaccines. Up to 30 days following Dose 4, serious adverse events were reported by 1.0% of VAXNEUVANCE recipients and by 0.7% of PCV13 recipients.

The safety and effectiveness of VAXNEUVANCE in individuals younger than 6 weeks of age have not been established.

Vaccination with VAXNEUVANCE may not protect all vaccine recipients.

We thank you for your business and your commitment to Merck Vaccines.

If you have any questions, please contact your Merck account representative, or call the Merck Vaccine Customer Center at 877-VAX-MERCK (877-829-6372).

Before administering VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine), 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 Merck representative.

Sincerely,

Merck Professional Services