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July 2026

Dear Health Care Professional,

We are writing to announce upcoming packaging updates for CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine).

Following the recent indication approval of CAPVAXIVE for use in appropriate children and adolescents, language on the product packaging will be updated.

Since June 2024, Merck has provided CAPVAXIVE with the following language on the product carton, "For use in individuals 18 years of age and older." On June 17, 2026, the US Food and Drug Administration approved an expanded indication for CAPVAXIVE to include children and adolescents 2 through 17 years of age who are at an increased risk of pneumococcal disease.

Accordingly, the product carton for CAPVAXIVE will be updated to reflect the expanded indication as follows: "**For use in individuals 18 years of age and older. For use in individuals 2 through 17 years of age at increased risk for pneumococcal disease."**

Cartons of CAPVAXIVE containing the updated language are expected to be available for distribution starting in October 2026. Regardless of package language, CAPVAXIVE can be used in appropriate children, adolescents, and adults, in alignment with the current Prescribing Information for CAPVAXIVE.

CAPVAXIVE will also soon be available in a single-dose option; additional information regarding the timing of this option will be provided at a later date. CAPVAXIVE continues to be available in cartons containing 10 single-dose prefilled syringes (NDC 0006-4347-02). The availability of both 1 single-dose and 10 single-dose cartons is intended to provide additional ordering flexibility to help meet customer needs. The single-dose prefilled 0.5 mL Luer Lock syringe of CAPVAXIVE (NDC 0006-4347-99) may be used for all approved ages.

Indications and Usage

CAPVAXIVE® is indicated for:

- active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older and individuals 2 through 17 years of age who are at increased risk for pneumococcal disease.
- active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.

The indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B is approved

under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Select Safety Information

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

Syncope may occur with administration of injectable vaccines.

Individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to CAPVAXIVE.

The most commonly reported (>10%) solicited adverse reactions in individuals 2 through 17 years of age who are at increased risk for pneumococcal disease were: injection-site pain (67.7%), injection-site erythema (24.3%), fatigue (20.1%), injection-site swelling (18.8%), headache (17.1%), malaise (13.3%), and irritability (11.6%).

The most commonly reported (>10%) solicited adverse reactions in individuals 18 through 49 years of age who received CAPVAXIVE were: injection-site pain (73.1%), fatigue (36.0%), headache (27.5%), myalgia (16.4%), injection-site erythema (13.8%), and injection-site swelling (13.3%).

The most commonly reported (>10%) solicited adverse reactions in individuals 50 years of age and older who received CAPVAXIVE were: injection-site pain (41.2%), fatigue (19.7%), and headache (11.0%).

The safety and effectiveness of CAPVAXIVE in individuals younger than 2 years of age have not been established.

Vaccination with CAPVAXIVE may not protect all vaccine recipients.

Dosage and Administration

Administer a single 0.5 mL dose.

CAPVAXIVE is a colorless, clear to opalescent solution. 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 intramuscularly.

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 CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine), please read the accompanying Prescribing Information. The Patient Information also is available.

Sincerely,

Merck Professional Services