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IMPORTANT PRESCRIBING INFORMATION

SUBJECT: Changes in the Prescribing Information for MENVEO [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine] to Describe Two Presentations

Date: October 14th, 2022

Dear Healthcare Provider,

MENVEO is a vaccine indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. The purpose of this letter is to alert you to changes in the MENVEO Prescribing Information. The Prescribing Information describes two presentations of MENVEO: the current two-vial presentation and a new one-vial presentation. Only the two-vial presentation is currently available. The new one-vial presentation will become available in mid-2023.

A summary of the presentations is described below:

- **Two-vial Presentation**
 - For use in individuals 2 months through 55 years of age
 - The two-vial presentation includes a vial with a gray cap containing the MenCYW-135 liquid conjugate component and a vial with an orange cap containing the MenA lyophilized conjugate component.
 - The contents of the vials must be combined to form MENVEO prior to administration.
- **One-vial Presentation**
 - For use in individuals 10 years through 55 years of age.
 - The one-vial presentation contains MENVEO in a single vial with a pink cap
 - This presentation does NOT require reconstitution.

Use **ONLY** the two-vial presentation for individuals 2 months through 9 years of age. Use **EITHER** presentation for individuals 10 years through 55 years of age.

Detailed information on both presentations is available in the enclosed [Prescribing Information](#).

To report SUSPECTED ADVERSE REACTIONS, contact GSK at 1-888-825-5249 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

You may also contact GSK Medical Information at 1-877-475-6448 if you have any questions about the information contained in this letter or the safe and effective use of MENVEO.

This letter is not intended as a complete description of the benefits and risks related to the use of MENVEO. Please refer to the enclosed Prescribing Information.

Sincerely,

A handwritten signature in black ink that reads "Diana E. Clements, MD". The signature is written in a cursive style and is positioned above a horizontal line.

Diana E. Clements, MD

Medical Director, Medical Affairs – Meningitis

Enclosure: MENVEO Full Prescribing Information