National Center for Immunization & Respiratory Diseases

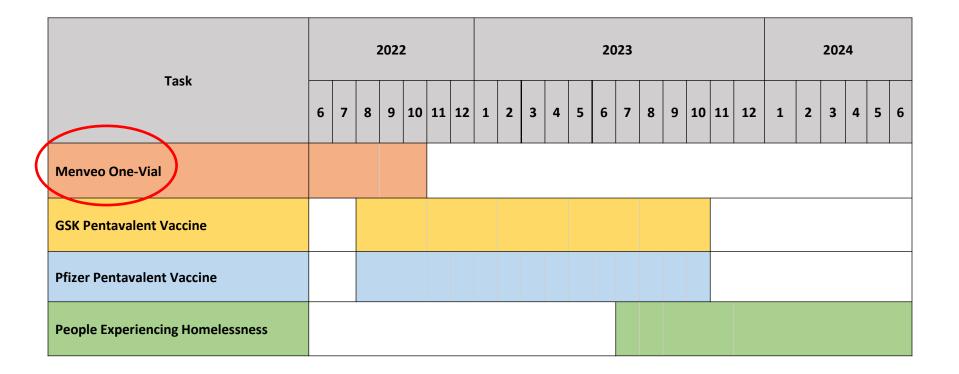


# **Menveo One-Vial Presentation**

Sam Crowe, PhD, MPH Work Group Lead

October 20, 2022

### **Project Timeline**



#### Background

- GSK has a newly licensed one-vial presentation of Menveo (MenACWY vaccine) that will be available in spring 2023
- Original and new versions of Menveo are nearly identical
  - GRADE/EtR not required
  - No ACIP or VFC vote required
- Products are licensed for different age ranges, raising important provider communication and use challenge

	Menveo Two-Vial (Original Product)	Menveo One-Vial (New Product)
Presentation	Two vials–MenCYW135 liquid andMenA lyophilized to be reconstituted in a 0.5mL dose	Single vial (0.5mL/dose) with all components in a liquid presentation ready to use
Age	2m–55y	10y–55y
Active substances (per 0.5mL)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GRM 197 (32.7 to 64.1 mcg)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GRM 197 (32.7 to 64.1 mcg)
Adjuvant and Preservatives	None	None
Excipients (per 0.5mL)		
Sodium chloride	4.5mg	4.5mg
Sodium dihydrogen phosphate	2.5mM	2.3mM
Disodium hydrogen phosphate dihydrate	7.5mM	7.7mM
Potassium dihydrogen phosphate	5mM	Not present
Sucrose	12.5mg	Not present
Water for injection	Q.S. to 0.5mL	Q.S. to 0.5mL

	Menveo Two-Vial (Original Product)	Menveo One-Vial (New Product)
Presentation	Two vials–MenCYW135 liquid andMenA lyophilized to be reconstituted in a 0.5mL dose	Single vial (0.5mL/dose) with all components in a liquid presentation ready to use
Age	2m–55y	10y–55y
Active substances (per 0.5mL)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GR 197 (32.7 to 64.1 mcg)	И Men A (10µg), C (5µg), W (5µg), Y (5µg), GRM 197 (32.7 to 64.1 mcg)
Adjuvant and Preservatives	None	None
Excipients (per 0.5mL)		
Sodium chloride	4.5mg	4.5mg
Sodium dihydrogen phosphate	2.5mM	2.3mM
Disodium hydrogen phosphate dihydrate	7.5mM	7.7mM
Potassium dihydrogen phosphate	5mM	Not present
Sucrose	12.5mg	Not present
Water for injection	Q.S. to 0.5mL	Q.S. to 0.5mL

	Menveo Two-Vial (Original Product)	Menveo One-Vial (New Product)
Presentation	Two vials–MenCYW135 liquid andMenA lyophilized to be reconstituted in a 0.5mL dose	Single vial (0.5mL/dose) with all components in a liquid presentation ready to use
Age	2m–55y	10y–55y
Active substances (per 0.5mL)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GRI 197 (32.7 to 64.1 mcg)	1 Men A (10µg), C (5µg), W (5µg), Y (5µg), G RM 197 (32.7 to 64.1 mcg)
Adjuvant and Preservatives	None	None
Excipients (per 0.5mL)		
Sodium chloride	4.5mg	4.5mg
Sodium dihydrogen phosphate	2.5mM	2.3mM
Disodium hydrogen phosphate dihydrate	7.5mM	7.7mM
Potassium dihydrogen phosphate	5mM	Not present
Sucrose	12.5mg	Not present
Water for injection	Q.S. to 0.5mL	Q.S. to 0.5mL

	Menveo Two-Vial (Original Product)	Menveo One-Vial (New Product)
Presentation	Two vials–MenCYW135 liquid andMenA lyophilized to be reconstituted in a 0.5mL dose	Single vial (0.5mL/dose) with all components in a liquid presentation ready to use
Age	2m–55y	10у–55у
Active substances (per 0.5mL)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GRM 197 (32.7 to 64.1 mcg)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GRM 197 (32.7 to 64.1 mcg)
Adjuvant and Preservatives	None	None
Excipients (per 0.5mL)		
Sodium chloride	4.5mg	4.5mg
Sodium dihydrogen phosphate	2.5mM	2.3mM
Disodium hydrogen phosphate dihydrate	7.5mM	7.7mM
Potassium dihydrogen phosphate	5mM	Not present
Sucrose	12.5mg	Not present
Water for injection	Q.S. to 0.5mL	Q.S. to 0.5mL

	Menveo Two-Vial (Original Product)	Menveo One-Vial (New Product)
Presentation	Two vials–MenCYW135 liquid andMenA lyophilized to be reconstituted in a 0.5mL dose	Single vial (0.5mL/dose) with all components in a liquid presentation ready to use
Age	2m–55y	10y–55y
Active substances (per 0.5mL)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GRM 197 (32.7 to 64.1 mcg)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GRM 197 (32.7 to 64.1 mcg)
Adjuvant and Preservatives	None	None
Excipients (per 0.5mL)		
Sodium chloride	4.5mg	4.5mg
Sodium dihydrogen phosphate	2.5mM	2.3mM
Disodium hydrogen phosphate dihydrate	7.5mM	7.7mM
Potassium dihydrogen phosphate	5mM	Not present
Sucrose	12.5mg	Not present
Water for injection	Q.S. to 0.5mL	Q.S. to 0.5mL

	Menveo Two-Vial (Original Product)	Menveo One-Vial (New Product)
Presentation	Two vials–MenCYW135 liquid andMenA lyophilized to be reconstituted in a 0.5mL dose	Single vial (0.5mL/dose) with all components in a liquid presentation ready to use
Age	2m–55y	10y–55y
Active substances (per 0.5mL)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GRM 197 (32.7 to 64.1 mcg)	Men A (10µg), C (5µg), W (5µg), Y (5µg), GRM 197 (32.7 to 64.1 mcg)
Adjuvant and Preservatives	None	None
Excipients (per 0.5mL)		
Sodium chloride	4.5mg	4.5mg
Sodium dihydrogen phosphate	2.5mM	2.3mM
Disodium hydrogen phosphate dihydrate	7.5mM	7.7mM
Potassium dihydrogen phosphate	5mM	Not present
Sucrose	12.5mg	Not present
Water for injection	Q.S. to 0.5mL	Q.S. to 0.5mL

#### **Provider Communication and Vaccine Use Challenge**

- Menveo Two-Vial presentation licensed for 2 months through 55 years
- Menveo One-Vial presentation licensed for 10 years through 55 years
- Other MenACWY vaccines available for young children
  - Menactra licensed for 9 months through 55 years (discontinued this summer)
  - MenQuadfi licensed for 2 years and older
- GSK plans to maintain a consistent but limited supply of Menveo Two-Vial for children <10 years</li>
- Challenge is to ensure that providers reserve Menveo Two-Vial for children <2 years</p>

## **Planned Communication Efforts**

GSK

- Will send provider letter to ensure physicians understand the differences between the two products
- Website will be updated with both the product information and the provider letter shortly after approval
- Menveo Two-Vial will be available through all traditional channels (VFC, wholesalers/distributors, and GSK Direct) in small order volumes
- Immunization Services Division, CDC
  - Updating the VFC resolution
  - Updating 2023 Child and Adolescent Immunization Schedule
  - Will conduct outreach with provider groups

For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

