

CLINICAL UPDATE

Brand Name	Meningococcal (Groups A, C, Y, W) Conjugate Vaccine
Generic Name	MenQuadfi®
Drug Manufacturer	Sanofi Pasteur Inc.

Clinical Update

Clinical Update: The U.S. Food and Drug Administration (FDA) has approved a Biologics License Application for MenQuadfi® Meningococcal (Groups A, C, Y, W) Conjugate Vaccine for the prevention of invasive meningococcal disease in persons 2 years of age and older.

FDA Approval Date: April 23, 2020

Launch Date: MenQuadfi® is expected to be available to providers and pharmacies nationwide in the U.S. for immunization efforts in 2021.

Overview

MenQuadfi® is the only U.S. FDA-approved quadrivalent meningococcal vaccine indicated for persons 2 through 56 years of age and older. MenQuadfi® is the first and only quadrivalent meningococcal vaccine in the U.S. that uses tetanus toxoid as a protein carrier. It will be available in a ready-to-use liquid formulation allowing healthcare providers to avoid vaccine reconstitution.

Efficacy

The FDA approval is based on clinical data from five double-blind, randomized, multicenter Phase 2 and 3 trials that assessed safety and immune responses following vaccination, with nearly 5,000 persons 2 years of age and older. Based on study objectives, immune responses elicited by MenQuadfi® achieved non-inferiority compared to those induced by licensed quadrivalent meningococcal vaccines. Four studies evaluated MenQuadfi® in meningococcal-naïve persons; the other study evaluated MenQuadfi® in persons previously immunized with a quadrivalent meningococcal vaccine. Against each of the four meningococcal serogroups (A, C, W, Y), the majority (55.4%–97.2%) of meningococcal-naïve trial participants had a vaccine-induced immune response 30 days following vaccination with MenQuadfi®. Among adolescents and adults previously vaccinated, 92.2%–98.2% demonstrated an immune response against each serogroup.

MenQuadfi® does not prevent N. meningitidis serogroup B disease.

Dose & Administration

Primary Vaccination

- Individuals 2 years of age and older: a single dose.

Booster Vaccination

- A single dose of MenQuadfi® may be administered to individuals 15 years of age and older who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of meningococcal (Groups A, C, W, Y) conjugate vaccine.

DOSAGE FORM(S) & STRENGTH(S)

Administer MenQuadfi® as a single 0.5 mL injection intramuscularly.

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