THE FUTURE OF MenACWY* PROTECTION, REIMAGINED

Indication[1]

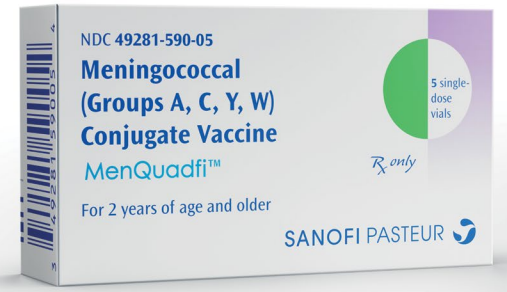
MenQuadfi is a vaccine indicated for active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y. MenQuadfi is approved for use in individuals 2 years of age and older. MenQuadfi does not prevent *N meningitidis* serogroup B disease.

MenQuadfi™ was developed through a novel serogroup-specific design[1,2]

- Tetanus toxoid (TT) was identified as an **alternative protein carrier** vs protein carriers used in other US-licensed MenACWY vaccines[1,2]
- **Individual conjugate structures** were evaluated for each serogroup (A, C, W, and Y)[1]
- **Chemical and structural features** for each serogroup achieved the demonstrated immune response[1]

Clinical features of MenQuadfi[1]

- **EXPANDED AGE GROUP:** MenQuadfi is the only MenACWY with an expanded age group for all individuals 2 years and older, including patients older than 55 years of age
- **APPROPRIATE FOR USE AS SECOND DOSE:** MenQuadfi can also be used for second-dose vaccination of patients 15 years of age or older who are at continued risk of meningococcal disease—even if the patient was primed with another licensed MenACWY vaccine—so long as at least 4 years have elapsed since the prior dose



For more information, contact your Sanofi Pasteur Sales Representative or call 1-800-VACCINE.
For more information, please visit MenQuadfi.com.

UNIQUE CODES: MenQuadfi has a **unique CPT®† code (90619)** and NDC code (49281-590-05)

SELECT IMPORTANT SAFETY INFORMATION

MenQuadfi should not be administered to anyone who has had a severe allergic reaction to any component of the vaccine, or after a previous dose of MenQuadfi or any other tetanus toxoid-containing vaccine.

Appropriate observation and medical treatment should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Please see full Important Safety Information on the back cover, and the accompanying full Prescribing Information in the pocket.

MenQuadfi™
Meningococcal (Groups A, C, Y, W) Conjugate Vaccine

REFINED PROTECTION

MENQUADFI™ DEMONSTRATED A HIGH IMMUNE RESPONSE ACROSS SEROGROUPS (A, C, W, AND Y)[1]

Head-to-head clinical trial with MenQuadfi vs Menveo® (Meningococcal [Groups A, C, Y, and W-135] Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine)

Immune non-inferiority, based on seroresponse, was demonstrated for MenQuadfi as compared to Menveo for all 4 serogroups.

Study design

The immunogenicity and safety of MenQuadfi in adolescents 10 through 17 years of age were evaluated in a randomized, head-to-head clinical trial vs Menveo involving more than 900 participants. Serum was collected at baseline and 30 days post-vaccination to measure antibodies with a serum bactericidal assay using human complement (hSBA). Solicited injection site and systemic reactions were recorded by participants daily for 7 days following vaccination. All unsolicited adverse events that occurred within 30 days following vaccination were recorded by participants, and all serious adverse events were collected for at least 6 months after vaccination.

Seroresponse rates 30 days post-vaccination

Seroresponse rates in adolescents 10 through 17 years of age ranged from 76% to 97% for MenQuadfi (N=462-463), and 66% to 81% for Menveo (N=463-464), across all 4 serogroups.

The percentage-point differences in seroresponse‡ rates—MenQuadfi minus Menveo (95% CI)—by serogroup were:

- Serogroup A: **+9%**§ (3% to 15%)[a]
- Serogroup C: **+25%**§ (20% to 29%)[a]
- Serogroup W: **+20%**§ (14% to 25%)[a]
- Serogroup Y: **+16%**§ (12% to 20%)[a]

Safety findings

Among the adolescent trial participants 10 through 17 years of age (N=982-987), the most common reactions following vaccination with MenQuadfi vs Menveo, respectively, were:

- Injection site pain (45.2% vs 42.5%)
- Myalgia (35.3% vs 35.2%)
- Headache (30.2% vs 30.9%)
- Malaise (26.0% vs 26.4%)

SELECT IMPORTANT SAFETY INFORMATION

Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to MenQuadfi. Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (eg, eculizumab) are at increased risk for invasive disease caused by *N meningitidis*, including invasive disease caused by serogroups A, C, W, and Y, even if they develop antibodies following vaccination with MenQuadfi.

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MenQuadfi™
Meningococcal (Groups A, C, Y, W) Conjugate Vaccine

REFINED PROTECTION

MENQUADFI™ DEMONSTRATED A HIGH IMMUNE RESPONSE ACROSS SEROGROUPS (A, C, W, AND Y)[1]

Head-to-head clinical trial with MenQuadfi vs Menactra® (Meningococcal [Groups A, C, Y and W-135] Polysaccharide Diphtheria Toxoid Conjugate Vaccine)[1]

Immune non-inferiority, based on seroresponse, was demonstrated for MenQuadfi as compared to Menactra for all 4 serogroups.

Study design[1,3]

The immunogenicity and safety of MenQuadfi were evaluated in a randomized, head-to-head clinical trial vs Menactra that included individuals 10-55 years of age (N=3344). Analyses were stratified by age, including a subpopulation consisting of nearly 1400 adolescents 10 through 17 years of age. Serum was collected at baseline and 30 days post-vaccination to measure antibodies with a serum bactericidal assay using human complement (hSBA). Solicited injection site and systemic reactions were recorded by participants daily for 7 days following vaccination. All unsolicited adverse events that occurred within 30 days following vaccination were recorded by participants, and all serious adverse events were collected for at least 6 months after vaccination.

Seroresponse rates 30 days post-vaccination[1,3,4]

In a secondary analysis of a subpopulation, in adolescents aged 10 through 17 years, seroresponse rates for MenQuadfi (N=1097-1098) ranged from 74% to 96%, and 53% to 86% for Menactra (N=300), across all 4 serogroups.

In the same secondary analysis of a subpopulation, the percentage-point differences in seroresponse[b] rates—MenQuadfi minus Menactra (95% CI)—by serogroup were:

- Serogroup A: **+19%**[§] (13% to 25%)[a]
- Serogroup C: **+42%**[§] (37% to 48%)[a]
- Serogroup W: **+13%**[§] (7% to 18%)[a]
- Serogroup Y: **+10%**[§] (6% to 15%)[a]

Safety findings[1]

Among the adolescent trial participants 10 through 17 years of age (N=1439-1473), the most common reactions following vaccination with MenQuadfi vs Menactra, respectively, were:

- Injection site pain (34.8% vs 41.4%)
- Myalgia (27.4% vs 31.2%)
- Headache (26.5% vs 28.0%)
- Malaise (19.4% vs 23.9%)

SELECT IMPORTANT SAFETY INFORMATION

Syncope can occur following, or even before, vaccination with MenQuadfi. Procedures should be in place to prevent falling and injury and to manage syncope.

Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of another US-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision to give MenQuadfi to persons with a history of GBS should take into account the expected benefits and potential risks.

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Meningococcal (Groups A, C, Y, W) Conjugate Vaccine

REFINED PROTECTION

FULL IMPORTANT SAFETY INFORMATION

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Appropriate observation and medical treatment should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to MenQuadfi. Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (eg, eculizumab) are at increased risk for invasive disease caused by *N meningitidis*, including invasive disease caused by serogroups A, C, W, and Y, even if they develop antibodies following vaccination with MenQuadfi.

Syncope can occur following, or even before, vaccination with MenQuadfi. Procedures should be in place to prevent falling and injury and to manage syncope.

Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of another US-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision to give MenQuadfi to persons with a history of GBS should take into account the expected benefits and potential risks.

Immunization with MenQuadfi does not substitute for routine tetanus immunization.

Vaccination with MenQuadfi may not protect all vaccine recipients.

The most common adverse reactions following a primary dose of MenQuadfi in individuals 2 years of age and older include pain at the injection site; myalgia, headache, and malaise. Other common adverse reactions in children 2 through 9 years of age include erythema and swelling at the injection site. In adolescents and adults, rates of solicited adverse reactions following a booster dose were comparable to those observed following primary vaccination. Other adverse reactions may occur.

Please see the accompanying full Prescribing Information in the pocket.

CI = Confidence internal; NDC = National Drug Code.

* MenACWY = Quadrivalent (serogroups A, C, W, and Y) meningococcal conjugate vaccine.

† CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association.

‡ Defined as the proportion of participants with an hSBA pre-vaccination titer <1:8 who achieved a post-vaccination titer ≥1:8, or participants with a pre-vaccination titer ≥1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer.

§ Percentage-point difference: MenQuadfi minus comparator (95% CI).

[a] 95% CI of the difference calculated from the Wilson Score method without continuity correction; the overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI is > -10% for all 4 serogroups.

[b] Defined as the proportion of participants with an hSBA pre-vaccination titer <1:8 who achieved a post-vaccination titer ≥1:16, or pre-vaccination titer ≥1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer.

References: 1. MenQuadfi [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc. **2.** Centers for Disease Control and Prevention (CDC). Vaccines and preventable diseases. https://www.cdc.gov/vaccines/vpd/mening/hcp/about-vaccine.html#types. Reviewed July 26, 2019. Accessed May 13, 2020. **3.** Dhingra MS, Peterson J, Hedrick J, et al. Immunogenicity, safety and inter-lot consistency of a meningococcal conjugate vaccine (MenACYW-TT) in adolescents and adults: A Phase III randomized study. *Vaccine*. 2020;38(33):5194-5201. **4.** Sanofi Pasteur Inc. Data on File. July 27, 2020.

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