HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use MenQuadfi® safely and effectively. See full prescribing information for MENQUADFI. MenQuadfi®; Meningococcal (Groups A, C, Y, W) Conjugate Vaccine Solution for Intramuscular Injection
Initial U.S. Approval: 2020

INDICATIONS AND USAGE
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. (1)

DOSAGE AND ADMINISTRATION
0.5 mL dose for intramuscular injection. (2)

Primary Vaccination
• Individuals 2 years of age and older: a single dose.

Booster Vaccination
• A single dose of MenQuadfi may be administered to individuals 13 years of age and older who are at continued risk for meningococcal disease if at least 3 years have elapsed since a prior dose of meningococcal (groups A, C, W, Y) conjugate vaccine.

Vaccination Following Prior Dose of Meningococcal Polysaccharide Vaccine

ADVERSE REACTIONS
Most commonly reported adverse reactions (≥10%) following a primary dose were as follows:
• Children 2 through 9 years of age, pain (38.6%), erythema (22.6%), and swelling (13.8%) at the injection site; malaise (21.1%), myalgia (20.1%), and headache (12.8%). (6)
• Adolescents aged 10 through 17 years of age, injection site pain (34.8%–45.2%), myalgia (27.4%–35.3%), headache (26.5%–30.2%), and malaise (19.4%–26.0%). (6)
• Adults aged 18 through 55 years, injection site pain (41.9%), myalgia (35.6%), headache (29.0%), and malaise (22.9%). (6)
• Adults 56 years of age and older, pain at the injection site (25.5%), myalgia (21.9%), headache (19.0%), and malaise (14.5%). (6)

In adolescents and adults, rates of solicited adverse reactions following a booster dose were comparable to those observed following primary vaccination. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc., Discovery Drive, Swiftwater, PA 18370 at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

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FULL PRESCRIBING INFORMATION
1 INDICATIONS AND USAGE
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 indicated for use in individuals 2 years of age and older. MenQuadfi does not prevent N. meningitidis serogroup B disease.

2 DOSAGE AND ADMINISTRATION
2.1 Preparation for Administration
MenQuadfi is a clear, colorless solution. Parenteral drug products should be inspected visually for particulate matter and/or discoloration prior to administration, whenever solution and container permit. If any of these conditions exist, the vaccine should not be administered. Discard the vial with any unused portion.

2.2 Dose and Schedule
Administer MenQuadfi as a single 0.5 mL injection intramuscularly. Primary Vaccination
• Individuals 2 years of age and older receive a single dose.

Booster Vaccination
• A single dose of MenQuadfi may be administered to individuals 13 years of age and older who are at continued risk for meningococcal disease if at least 3 years have elapsed since a prior dose of meningococcal (groups A, C, W, Y) conjugate vaccine.

Vaccination Following Prior Dose of Meningococcal Polysaccharide Vaccine
• A single dose of MenQuadfi may be administered if at least 3 years have elapsed since a prior dose of meningococcal polysaccharide vaccine.

3 DOSAGE FORMS AND STRENGTHS
MenQuadfi is a sterile solution for intramuscular injection supplied in 0.5 mL single-dose vials.

4 CONTRAINDICATIONS
Severe allergic reaction to any component of the vaccine, or after a previous dose of MenQuadfi or any other tetanus toxoid-containing vaccine. (4)

5 WARNINGS AND PRECAUTIONS
5.1 Management of Acute Allergic Reactions
Appropriate observation and medical treatment should always be readily available in case of an anaphylactic event following the administration of the vaccine.

5.2 Altered Immunocompetence
Reduced Immune Response
Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to MenQuadfi. Complement Deficiency
Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, 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. (12)

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

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
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5.4 Guillain–Barre Syndrome

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

5.5 Tetanus Immunization

Immunization with MenQuadfi does not substitute for routine tetanus immunization.

5.6 Limitations of Vaccine Effectiveness

Vaccination with MenQuadfi may not protect all vaccine recipients.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trial(s) of a vaccine cannot be directly compared to rates in the clinical trial(s) of another vaccine and may not reflect the rates observed in practice. The safety of a single dose of MenQuadfi in individuals 2 years of age and older was evaluated in seven randomized, active-controlled, multi-center clinical studies conducted in the US and Puerto Rico. In these studies, a total of 5,787 participants received either a primary dose (N = 4,517), a booster dose (N = 1,119) of MenQuadfi following priming with a meningococcal conjugate vaccine, or a dose of MenQuadfi following a prior dose of meningococcal polysaccharide vaccine (N = 151) and were included in the safety analyses.

Safely Monitoring

Participants were monitored for immediate reactions for 30 minutes following vaccination while at the study site. Solicited injection site and systemic reactions were recorded by participants or by parents/guardians in a diary card at home daily for 7 days following vaccination. All unsolicited adverse events that occurred within 30 days following vaccination were recorded by participants or by parents/guardians and collected by the study site at the next visit. Unsolicited adverse events that were medically attended (i.e., visits to an emergency room, or an unexpected visit to a health care provider), and all serious adverse events (SAEs) were collected for at least 6 months after vaccination for all studies except Study 7 [NCT04142242], in which these safety data were collected for at least 1 month.

Primary Vaccination

Children 2 through 9 years of age

The safety of MenQuadfi in children 2 years through 9 years of age was evaluated in Study 1 (NCT03077438). The analysis set included 498 participants who received MenQuadfi and 494 participants who received Menveo® [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM® Conjugate Vaccine]. Of the participants 2 through 9 years of age who received MenQuadfi (N = 498), 50.2% were between 5 years of age, 49.8% were 6 through 9 years of age, 49.0% were female, 80.5% were White, 13.3% were Black or African American, 0.4% were Asian, 5.2% were of other racial groups, and 22.9% were of Hispanic or Latino ethnicity. There were no substantive differences in demographic characteristics between the vaccine groups. The rates and severity of the solicited adverse reactions that occurred within 7 days following MenQuadfi compared with Menveo (Study 1) are presented in Table 1. SAEs occurred at a rate of 1.4% following MenQuadfi and at a rate of 0.6% following Menveo during the entire study period. Most SAEs occurred more than 30 days following vaccination and were commonly occurring events in the general population in this age group. No SAEs were determined to be vaccine related.

Adolescents 10 through 17 years of age

The safety of MenQuadfi in adolescents 10 through 17 years of age was evaluated in two clinical trial studies Study 2 (NCT02199691) and Study 3 (NCT02842853). The safety analysis set in these two studies included 3,196 participants who received MenQuadfi alone (1,684 participants), MenQuadfi concomitantly with Adacel® [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed] (Tdap) and Gardasil® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] (HPV) (392 participants), the concomitant vaccines without MenQuadfi (296 participants), or a U.S.-licensed comparator meningococcal vaccine (824 participants). The comparator meningococcal vaccine was either Menveo (501 participants) or Menactra® [Meningococcal (Groups A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine] (323 participants).

Of the participants 10 through 17 years of age who received MenQuadfi (N = 1,684), 19.6% were female. Among those with reported race and ethnicity, 79.3% were White, 14.2% were Black or African American, 1.1% were Asian, 5.4% were of other racial groups, and 21.5% were of Hispanic or Latino ethnicity. Mean age was 11.9 years at time of administration. There were no substantive differences in demographic characteristics between the vaccine groups.

The rates and severity of the solicited adverse reactions that occurred within 7 days following MenQuadfi compared with Menveo and Menactra are presented in Table 2. The most common injection site and systemic reactions occurring after MenQuadfi administration (in Study 2 and Study 3) were injection site pain (45.2% and 34.8%) and myalgia (35.3% and 27.4%), respectively.

In Study 2, SAEs occurred at a rate of 0.8% following MenQuadfi and 0.8% following Menveo. In Study 3, SAEs occurred at a rate of 0.3% following MenQuadfi and 0.9% following Menactra. No SAEs were determined to be vaccine related.

Table 1: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days After Vaccination with MenQuadfi or Menveo in Children 2 through 9 Years of Age (Study 1)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi (N=484-487)</th>
<th>Menveo (N=479-486)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td>Any</td>
<td>Grade 3</td>
</tr>
<tr>
<td>Injection Site Pain</td>
<td>38.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Injection Site Erythema</td>
<td>22.6</td>
<td>3.1</td>
</tr>
<tr>
<td>Injection Site Swelling</td>
<td>13.8</td>
<td>1.4</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td>Myalgia†</td>
<td>20.1</td>
</tr>
<tr>
<td></td>
<td>Malaise§</td>
<td>21.1</td>
</tr>
<tr>
<td></td>
<td>Headache§</td>
<td>12.5</td>
</tr>
<tr>
<td></td>
<td>Fever‡</td>
<td>1.9</td>
</tr>
</tbody>
</table>

†Clinical trial identifier NCT02199691
§Clinical trial identifier NCT02842853
¶Any: > 100.4°F (38.0°C); Grade 3: > 102.1°F (39.0°C)

Table 2: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days After Vaccination with MenQuadfi or Menveo in Individuals 10 through 17 Years of Age (Study 2) and MenQuadfi or Menactra in Individuals 10 through 17 Years of Age (Study 3)

<table>
<thead>
<tr>
<th>Study</th>
<th>MenQuadfi (N=1,684-1,979)</th>
<th>Menveo (N=1,684-1,979)</th>
<th>MenQuadfi (N=1,129-1,159)</th>
<th>Menactra (N=310-314)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>Grade 3</td>
<td>Any</td>
<td>Grade 3</td>
<td>Any</td>
</tr>
<tr>
<td>Local Reactions</td>
<td>Injection Site Pain</td>
<td>45.2</td>
<td>0.4</td>
<td>42.5</td>
</tr>
<tr>
<td>Injection Site Erythema</td>
<td>5.0</td>
<td>0.4</td>
<td>7.5</td>
<td>1.2</td>
</tr>
<tr>
<td>Injection Site Swelling</td>
<td>5.4</td>
<td>0.2</td>
<td>6.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td>Myalgia</td>
<td>35.3</td>
<td>1.6</td>
<td>35.2</td>
</tr>
<tr>
<td></td>
<td>Malaise</td>
<td>30.2</td>
<td>1.8</td>
<td>30.9</td>
</tr>
<tr>
<td></td>
<td>Fever</td>
<td>1.4</td>
<td>0.4</td>
<td>1.2</td>
</tr>
</tbody>
</table>

Among 296 participants who received Tdap and HPV concomitantly (without MenQuadfi) and 392 participants who received MenQuadfi concurrently with Tdap and HPV, there were no notable differences in the rates of systemic solicited adverse reactions within 7 days following vaccination.

Dizziness within 30 minutes following vaccination was experienced by 1 (0.2%) participant who received MenQuadfi in Study 2 (NCT02199691) and 2 (0.2%) participants who received MenQuadfi in Study 3 (NCT02842853). These 3 participants in Study 2 experienced syncope within 30 minutes following vaccination: 1 (0.2%) participant who received Menveo, 1 (0.3%) participant who received MenQuadfi concomitantly with Tdap and HPV, and 1 (0.3%) participant who received Tdap and HPV concomitantly (without MenQuadfi). These events were non-serious and spontaneously resolved on the same day.

Adolescents 18 through 55 years of age

The safety of MenQuadfi in adults 18 through 55 years of age was evaluated in Study 3 (NCT02842853). The safety analysis set included 1,495 participants who received MenQuadfi and 312 participants who received Menactra. Of the participants 18 through 55 years of age who received MenQuadfi (N = 1,495), 65.2% were female. Among those with reported race and ethnicity, 73.3% were White, 21.0% were Black or African American, 2.2% were Asian, 3.5% were of other racial groups, and 20.0% were of Hispanic or Latino ethnicity. Mean age was 39.4 years at time of administration. There were no substantive differences in demographic characteristics between the vaccine groups.
SAEs occurred at a rate of 1.6% following MenQuadfi and at a rate of 0.6% following Menactra during the entire study period. No SAEs were determined to be vaccine related.

Table 3: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Vaccination with MenQuadfi or Menactra in Individuals 16 through 55 Years of Age (Study 3)†

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi (N=1,441-1,460)</th>
<th>Menactra (N=297-301)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Site Paina</td>
<td>41.9 (1.9)</td>
<td>35.0 (1.3)</td>
</tr>
<tr>
<td>Injection Site Erythemaa</td>
<td>5.1 (0.3)</td>
<td>3.7 (0.3)</td>
</tr>
<tr>
<td>Injection Site Swellinga</td>
<td>4.3 (0.2)</td>
<td>3.4 (0.3)</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgiab</td>
<td>35.6 (3.6)</td>
<td>31.2 (2.3)</td>
</tr>
<tr>
<td>Headacheb</td>
<td>29.0 (2.9)</td>
<td>27.6 (2.7)</td>
</tr>
<tr>
<td>Malaiseb</td>
<td>22.9 (2.9)</td>
<td>18.9 (3.3)</td>
</tr>
<tr>
<td>Feverb</td>
<td>1.4 (0.1)</td>
<td>1.7 (0.7)</td>
</tr>
</tbody>
</table>

*Clinical trial identifier NCT02842853
†N is the number of vaccinated participants with available data for the events listed
‡Grade 3: Prevents daily activity
§Any: > 25 mm; Grade 3: > 100 mm
¶Any: ≥ 100.4°F (38.0°C); Grade 3: ≥ 102.1°F (39.0°C)

Adults 56 years of age and older

The safety of MenQuadfi in adults 56 years of age and older was evaluated in Study 4 (NCT02842866). The safety analysis set included 448 participants who received MenQuadfi intramuscularly and 453 participants who received a non-conjugate comparator meningococcal vaccine, Menomune® – A/C/YW-135 [Meningococcal Polysaccharide Vaccine, Groups A, C, Y, and W-135 Combined], subcutaneously. Of the participants 56 years of age and older who received MenQuadfi (N = 448), 44.4% were 56 through 64 years of age, 55.6% were 65 years of age and older, 57.6% were female, 86.6% were White, 11.6% were Black or African American, 1.1% were Asian, 0.4% were of other racial groups and 7.6% were of Hispanic or Latino ethnicity. Mean age was 76.7 years at time of administration.

The rates and severity of the solicited adverse reactions that occurred within 7 days following MenQuadfi compared with Menomune in Study 4 (NCT02842866) are presented in Table 4. SAEs occurred at a rate of 3.3% following MenQuadfi and at a rate of 3.3% following Menomune during the entire study period. No SAEs were determined to be vaccine related.

Table 4: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Vaccination with MenQuadfi or Menomune in Individuals 56 Years of Age and Older (Study 4)†

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi (N=436-443)</th>
<th>Menomune (N=449-451)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Site Paina</td>
<td>25.5 (0.7)</td>
<td>9.6 (0.7)</td>
</tr>
<tr>
<td>Injection Site Erythemaa</td>
<td>5.2 (0.2)</td>
<td>0.0 (0.0)</td>
</tr>
<tr>
<td>Injection Site Swellinga</td>
<td>4.5 (0.0)</td>
<td>0.0 (0.0)</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgiab</td>
<td>21.9 (1.6)</td>
<td>15.3 (1.3)</td>
</tr>
<tr>
<td>Headacheb</td>
<td>19.0 (0.7)</td>
<td>14.6 (0.7)</td>
</tr>
<tr>
<td>Malaiseb</td>
<td>14.5 (1.4)</td>
<td>11.3 (1.8)</td>
</tr>
<tr>
<td>Feverb</td>
<td>2.1 (0.2)</td>
<td>0.4 (0.0)</td>
</tr>
</tbody>
</table>

*Clinical trial identifier NCT02842866
†N is the number of vaccinated participants with available data for the events listed
‡Menomune was given subcutaneously
§Grade 3: Prevents daily activity
¶Any: > 25 mm; Grade 3: > 100 mm
≥Any: ≥ 100.4°F (38.0°C); Grade 3: ≥ 102.1°F (39.0°C)

Booster Vaccination Following Priming with a Meningococcal Conjugate Vaccine; Vaccination Following a Prior Dose of a Meningococcal Polysaccharide Vaccine

Adolescents and adults 15 years of age and older

The safety of MenQuadfi in previously vaccinated adolescents and adults 15 years of age and older was evaluated in Study 5 (NCT02752906). All randomized participants had received a primary dose of either (Menveo or Menactra) 4 to 10 years previously. The safety analysis set included 402 participants who received a single booster dose of MenQuadfi (median age: 17.8 years) and 407 participants who received a single booster dose of Menactra (median age: 17.9 years). Of the participants who received MenQuadfi, 51.5% were female, 85.1% were White, 9.7% were Black, 2.7% were of other racial groups, and 15.7% were of Hispanic or Latino ethnicity.

The most commonly reported solicited adverse reactions (≥10%) within 7 days of MenQuadfi booster vaccination were injection site pain (44.7%), headache (37.9%), myalgia (36.7%), and malaise (27.6%). The majority of solicited adverse reactions were Grade 1 or 2 and resolved within 3 days. Compared with recipients of a Menactra booster dose, recipients of a MenQuadfi booster dose had higher rates of injection site erythema (MenQuadfi 5.0%, Menactra 1.5%) and swelling (MenQuadfi 4.0%, Menactra 0.7%). Overall rates of solicited adverse reactions were comparable to those observed in unvaccinated adolescents and adults after a single MenQuadfi dose. SAEs occurred at a rate of 1.2% following MenQuadfi and at a rate of 1.0% following Menactra during the entire study period. No SAEs were determined to be vaccine related.

Adolescents and adults 13 through 26 years of age

The safety of MenQuadfi in previously vaccinated adolescents and adults 13 through 26 years of age was evaluated in Study 6 (NCT04084769). All randomized participants had received a primary dose of either MenQuadfi or Menveo 3-6 years previously. The safety analysis set included 370 participants who received a booster dose of MenQuadfi alone (median age: 15.0 years for subjects primed with MenQuadfi and 16.0 years for subjects primed with Menveo) and 185 participants who received MenQuadfi concomitantly with Trumenba® [Meningococcal Group B Vaccine] (N=93, median age: 15.0 years) or Bexsero® [Meningococcal Group B Vaccine] (N=92; median age: 15.0 years). Of the participants who received a booster dose of MenQuadfi, 47.2% were female, 88.1% were White, 8.2% were Black, 3.8% were of other racial groups, and 14.4% were of Hispanic or Latino ethnicity.

The rates and severity of the solicited adverse reactions that occurred within 7 days following a booster dose of MenQuadfi alone or concomitantly with Trumenba or Bexsero in Study 6 (NCT04084769) are presented in Table 5. The majority of solicited reactions were Grade 1 or 2 and resolved within 3 days after vaccination.

There were no reported SAEs that were assessed as vaccine related.

Table 5: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Booster Vaccination with MenQuadfi Alone or MenQuadfi Concomitantly Administered with Trumenba or Bexsero in Individuals 13 Through 26 Years of Age Who Had Received a Primary Dose of MenQuadfi or Menveo 3-6 Years Previously (Study 6)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi in MenQuadfi-primed (N=96) %</th>
<th>MenQuadfi in Menveo-primed (N=51) %</th>
<th>MenQuadfi and Trumenba in MenQuadfi-primed (N=94) %</th>
<th>MenQuadfi and Bexsero in MenQuadfi-primed (N=92) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Site Pain</td>
<td>38.2 (0.5)</td>
<td>33.7 (1.1)</td>
<td>48.9 (5.4)</td>
<td>56.5 (0)</td>
</tr>
<tr>
<td>Injection Site Erythema</td>
<td>6.5 (0.5)</td>
<td>5.4 (0)</td>
<td>1.1 (0)</td>
<td>6.5 (1.1)</td>
</tr>
<tr>
<td>Injection Site Swelling</td>
<td>5.4 (0)</td>
<td>1.6 (0)</td>
<td>2.2 (0)</td>
<td>5.4 (1.1)</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td>32.8 (1.6)</td>
<td>34.8 (1.1)</td>
<td>65.2 (7.6)</td>
<td>63.0 (4.3)</td>
</tr>
<tr>
<td>Headache</td>
<td>36.0 (1.1)</td>
<td>34.8 (1.6)</td>
<td>42.4 (4.3)</td>
<td>39.1 (2.2)</td>
</tr>
<tr>
<td>Malaise</td>
<td>26.9 (2.2)</td>
<td>25.5 (2.2)</td>
<td>39.1 (5.4)</td>
<td>40.2 (3.3)</td>
</tr>
<tr>
<td>Fever</td>
<td>0 (0)</td>
<td>2.2 (0.5)</td>
<td>1.1 (0)</td>
<td>4.4 (0)</td>
</tr>
</tbody>
</table>

*Clinical trial identifier NCT04084769
†Local reactions attributed to administration of MenQuadfi

Older adults ≥ 59 years of age

The safety of MenQuadfi in previously vaccinated older adults ≥ 59 years of age was evaluated in Study 7 (NCT04142242). All randomized participants had received a prior dose of either MenQuadfi (N=162) or Menomune (N=151) at a median interval of 3.34 and 3.35 years, respectively. The safety analysis set included 313 participants who received a dose of MenQuadfi (median age: 69.0 years for subjects primed with MenQuadfi and 70.0 years for subjects who received a prior dose of Menomune); 62.6% were female, 90.4% were White, 8.6% were Black, 0.3% were of other racial groups, and 10.5% were of Hispanic or Latino ethnicity.
The rates and severity of the solicited adverse reactions that occurred within 7 days following a dose of MenQuadfi in Study 7 (NCT04142242) are presented in Table 8. The majority of solicited reactions were Grade 1 or 2 and resolved within 3 days after vaccination. There were no reported SAEs that were assessed as vaccine related.

Table 6: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Vaccination with MenQuadfi in Individuals ≥ 59 Years of Age Who Had Received a Prior Dose of MenQuadfi or Menomune At Least 3 Years Previously (Study 7)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi-primed (N=162)</th>
<th>Prior dose of Menomune (N=151)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>Any</td>
</tr>
<tr>
<td><strong>Local Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Site Pain</td>
<td>16.7</td>
<td>0</td>
</tr>
<tr>
<td>Injection Site Erythema</td>
<td>3.7</td>
<td>0</td>
</tr>
<tr>
<td>Injection Site Swelling</td>
<td>3.7</td>
<td>0</td>
</tr>
<tr>
<td><strong>Systemic Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td>21.6</td>
<td>2.5</td>
</tr>
<tr>
<td>Headache</td>
<td>18.5</td>
<td>0</td>
</tr>
<tr>
<td>Malaise</td>
<td>13.6</td>
<td>1.9</td>
</tr>
<tr>
<td>Fever</td>
<td>0.6</td>
<td>0</td>
</tr>
</tbody>
</table>

N: number of participants in the safety analysis set
*Clinical trial identifier NCT04142242

7 DRUG INTERACTIONS
7.1 Concomitant Administration with Other Vaccines
In a clinical trial in adolescents 10 through 17 years of age, MenQuadfi was administered concomitantly with Tdap and HPV [see Adverse Reactions (6) and Clinical Studies (14.3)]. Lower geometric mean antibody concentrations (GMCS) for antibodies to the pertussis antigens filamentous hemagglutinin (FHA), pertactin (PRN) and fimbriae (FIM) were observed when MenQuadfi was co-administered with Tdap and HPV compared to concomitant administration of Tdap and HPV without MenQuadfi [see Clinical Studies (14.3)].

7.2 Immunosuppressive Treatments
Immunosuppressive therapies may reduce the immune response to MenQuadfi [see Warnings and Precautions (5)].

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Exposure Registry
There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to MenQuadfi during pregnancy. To enroll in or obtain information about the registry, call Sanofi Pasteur at 1-800-822-2463.

Risk Summary
All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

There are no clinical studies of MenQuadfi in pregnant women. Available human data on MenQuadfi administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. A developmental toxicity study in female rabbits administered a full human dose (0.5 mL) prior to mating and during gestation period revealed no evidence of harm to the fetus due to MenQuadfi [see Animal Data].

Data
Animal Data
In a developmental toxicity study, female rabbits received a human dose of MenQuadfi by intramuscular injection on five occasions: 30 days and 10 days prior to mating, gestation days 6, 12 and 27. No adverse effects on pre-weaning development up to post-natal day 35 were observed. There were no vaccine-related fetal malformations or variations observed.

8.2 Lactation
Risk Summary
It is not known whether MenQuadfi is excreted in human milk. Data are not available to assess the effects of MenQuadfi on the breastfed infant or on milk production/excretion. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for MenQuadfi and any potential adverse effects on the breastfed child from MenQuadfi or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use
Safety and effectiveness of MenQuadfi have not been established in individuals younger than 2 years of age in the US.

8.5 Geriatric Use
A total of 249 participants 65 years of age and older, including 71 participants 75 years of age or older, in Study 4 received one dose of MenQuadfi [see Adverse Reactions (6.1) and Clinical Studies (14.1)].

MenQuadfi recipients ≥ 65 years of age had lower GMTs and seroreponse rates for all serogroups compared to MenQuadfi recipients 56 through 64 years of age [see Clinical Studies (14.1)].

11 DESCRIPTION
MenQuadfi is a sterile liquid vaccine administered by intramuscular injection that contains Neisseria meningitidis serogroup A, C, W, and Y capsular polysaccharide antigens that are individually conjugated to tetanus toxoid protein, N. meningitidis A, C, W, and Y strains are cultured on Mueller Hinton agar medium and grown in Watson Scherp medium. The polysaccharides are extracted from the N. meningitidis cells and purified by centrifugation, detergent precipitation, alcohol precipitation, solvent extraction, and dialfiltration. To prepare the polysaccharides for conjugation, Serogroup A is activated with carbonyldimidazole (CDI), derivatized with adipic acid dihydrazide (ADH), and purified by dialfiltration. Serogroups C, W, and Y are depolymerized, activated with peridate, and purified by dialfiltration.

Clostridium tetani is fermented in media to generate tetanus toxin, which is purified by ammonium sulfate precipitation to yield purified tetanus toxin (PTT) and detoxified with formaldehyde to yield purified tetanus protein (PTP). The PTP is then concentrated and filtered to yield concentrated tetanus protein (CTP). The activated/dervatized polysaccharides are covalently linked to tetanus toxoid and purified by chromatography and serial dialfiltration. The four meningococcal components, present as individual serogroup-specific glycoconjugates, compose the final formulated vaccine.

MenQuadfi is manufactured as a sterile, clear, colorless solution. Each 0.5 mL dose of vaccine contains 10 microgram each of meningococcal A, C, W and Y polysaccharide antigens conjugated to approximately 55 micrograms tetanus toxoid protein carrier; 3.35 mg sodium chloride (0.67%), and 1.23 mg sodium acetate (30 mM). Potency of MenQuadfi is determined by quantifying the amount of each polysaccharide antigen that is conjugated to tetanus toxoid protein and the amount of unconjugated polysaccharide present.

No preservative or adjuvant is added during manufacturing. Each 0.5 mL dose may contain residual amounts of formaldehyde of less than 3 mcg/mL, by calculation. The vial in which the vaccine components are contained is composed of USP Type I borosilicate glass. The vial stopper is a chlorobutyl synthetic polyisoprene blend stopper (not made with natural rubber latex).

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Invasive meningococcal disease (IMD) is caused by the bacterium N. meningitidis, a gram-negative diplococcus found exclusively in humans. The presence of bacterial anti-capsular meningococcal antibodies in serum has been associated with protection from IMD. MenQuadfi induces the production of bactericidal antibodies specific to the capsular polysaccharides of N. meningitidis serogroups A, C, W, and Y.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
MenQuadfi has not been evaluated for carcinogenic or mutagenic potential or for impairment of male fertility. MenQuadfi administered to female rabbits had no effects on fertility [see Use in Specific Populations (8.1)].

14 CLINICAL STUDIES
To infer effectiveness of MenQuadfi, the immunogenicity in persons 2 years of age and older was evaluated using a serogroup-specific serenic bacterial assay with exogenous human complement (hSBA). The hSBA responses following a single dose of MenQuadfi for primary vaccination were assessed in four studies, and the hSBA responses following a single dose of MenQuadfi for booster vaccination were assessed in two studies. The hSBA responses following a single dose of MenQuadfi were also assessed in one study that enrolled a group of participants who had received a prior dose of meningococcal capsular polysaccharide vaccine. Serum was collected at baseline and 30 days post-vaccination to measure antibodies with hSBA. The hSBA geometric mean titers (GMTs) and proportion of participants who achieved hSBA seropositive (defined below) were evaluated.

- Seropositive rate for each serogroup: the proportion of participants with an hSBA titer greater than the pre-vaccination titer.
- 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.

14.1 Primary Vaccination
Immunogenicity in Children 2 through 9 Years of Age
Immunogenicity of MenQuadfi compared to Menveo in participants 2 through 9 years of age was evaluated in Study 1 (NCT03077438). The hSBA seropositive rate and GMTs are presented in Table 7.

Immune non-inferiority, based on seropositive rates, was demonstrated for MenQuadfi as compared to Menveo for all four serogroups.

Table 7: Comparison of Bactericidal Antibody Responses to MenQuadfi and Menveo 30 Days After Vaccination of Participants 2 through 9 Years of Age

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>MenQuadfi (95% CI)</th>
<th>Menveo (95% CI)</th>
<th>Percent difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>N=455-456</td>
<td>N=456</td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seropositive</td>
<td>1.1, 14.0</td>
<td>47.4</td>
<td>7.6</td>
</tr>
<tr>
<td>B</td>
<td>50.7; 60.0</td>
<td>43.2; 52.5</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>25</td>
<td>20.2</td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seropositive</td>
<td>(22; 28)</td>
<td>(11; 14)</td>
<td>47.4</td>
</tr>
<tr>
<td>D</td>
<td>N=458</td>
<td>N=458-459</td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seropositive</td>
<td>97.0</td>
<td>52.1</td>
<td>47.4</td>
</tr>
</tbody>
</table>
Seroresponse rate (primary endpoint) for each serogroup: the proportion of participants with an hSBA pre-vaccination titer ≥1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer.

Overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI is >-10% for all four serogroups.

Immunogenicity in Adolescents 10 through 17 Years of Age
Immunogenicity of MenQuadfi compared to Menveo in participants 10 through 17 years of age was evaluated in Study 2 (NCT02199691). Study 2 was conducted in healthy meningococcal vaccine naïve participants and evaluated seroresponse rates following administration with either MenQuadfi alone, Menveo alone, MenQuadfi co-administered with Tdap, and HPV, or Tdap and HPV alone. The hSBA seroresponse rate and GMTs for Study 2 are presented in Table 8.

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

Study 2 evaluated the immunogenicity of MenQuadfi (N=1097-1098) compared to Menactra (N=300) in healthy meningococcal-naïve participants 10 through 17 years of age. Seroresponse rates for MenQuadfi were noninferior to those of Menactra for all serogroups based on the same non-inferiority criteria defined for Study 2.

Immunogenicity in Adults 18 through 55 Years of Age
Immunogenicity of MenQuadfi compared to Menactra in participants 18 through 55 years of age was evaluated in Study 3 (NCT02942853). The hSBA seroresponse rate and GMTs are presented in Table 9.

Seroresponse rate (primary endpoint) for each serogroup: 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.

Overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI is > -10% for all four serogroups.

Immunogenicity in Adults 56 Years of Age and Older
Immunogenicity of MenQuadfi compared to Menomune in participants 56 years and older was evaluated in Study 4 (NCT02842866).
Enrollment was stratified by age category: 56 through 64 years of age (44.3%), 65 through 74 years of age (39.7%), and 75 years of age and older (15.9%). The overall mean age of participants who received MenQuadfi was 66.9 years; range: 56 through 89.8 years of age. The mean age for participants in the 56 through 64 years stratum who received MenQuadfi was 72.2 years. The hSBA seroresponse rate and GMTs are presented in Table 10. Immune non-inferiority, based on seroresponse rates, was demonstrated for MenQuadfi as compared to Menomune for all four serogroups.

### Table 10: Comparison of Bactericidal Antibody Responses to MenQuadfi and Menomune in Naïve Older Adults and Elderly 30 Days After Vaccination (Study 4)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>MenQuadfi (95% CI)</th>
<th>Menomune (95% CI)</th>
<th>Percent difference MenQuadfi minus Menomune (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>58.2 (53.4, 62.9)</td>
<td>42.5 (37.7, 47.3)</td>
<td>15.7 (9.08, 22.2)</td>
</tr>
<tr>
<td>GMT</td>
<td>55</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>77.1 (72.9, 81.0)</td>
<td>49.7 (44.8, 54.5)</td>
<td>27.5 (21.2, 33.5)</td>
</tr>
<tr>
<td>GMT</td>
<td>101 (84, 123)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>W</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>62.6 (57.8, 67.2)</td>
<td>44.8 (40.0, 49.6)</td>
<td>17.8 (11.2, 24.2)</td>
</tr>
<tr>
<td>GMT</td>
<td>28</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>74.4 (70.0, 78.4)</td>
<td>43.4 (38.7, 48.2)</td>
<td>31.0 (24.6, 37.0)</td>
</tr>
<tr>
<td>GMT</td>
<td>69</td>
<td>21</td>
<td></td>
</tr>
</tbody>
</table>

N: number of participants in per-protocol analysis set with valid serology results. 95% CI of the single proportion calculated from the exact binomial method. 95% CI of the difference calculated from the Wilson Score method without continuity correction.

*Clinical trial identifier NCT02842866
†Seroresponse rate (primary endpoint) for each serogroup: 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.
‡The overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI is > -10% for all four serogroups.

### 14.2 Booster Vaccination Following Priming with a Meningococcal Conjugate Vaccine

Vaccination Following a Prior Dose of a Meningococcal Polysaccharide Vaccine

Immunogenicity in Adolescents and Adults at least 15 Years of Age and Older

Immunogenicity of a booster dose of MenQuadfi compared to a booster dose of Menactra was evaluated in Study 5 (NCT02752906). The study-enrolled participants 15 years of age and older who had received a primary dose of Menomune or Menactra 4 to 10 years previously. Immune non-inferiority, based on seroresponse rates, was demonstrated for MenQuadfi as compared to Menactra for all four serogroups.

For a description of study design and number of participants, see section 6.1 Booster Vaccination Following Priming with a Meningococcal Conjugate Vaccine. Vaccination Following a Prior Dose of a Meningococcal Polysaccharide Vaccine. The primary immunogenicity endpoint was hSBA seroresponse to each serogroup 30 days following booster vaccination with MenQuadfi or Menactra given to participants who received a prior dose of Menomune or Menactra 4 to 10 years ago. The other endpoints included the proportions of participants with post-vaccination hSBA ≥ 1:8 and the hSBA GMTs for each serogroup. These endpoints were also evaluated at 6 days post vaccination in a subset. Seroresponse rates at Day 6 following booster dose with MenQuadfi were 86.2%, 89.1%, 97.8%, and 95.7% for serogroups A, C, W, and Y, respectively. In MenQuadfi-primed participants (N=46) and 77.6%, 93.3%, 89.9%, and 91.1% for serogroups A, C, W, and Y, respectively. In Menveo-primed participants (N=45). Following a booster dose of MenQuadfi, the hSBA GMTs at Day 6 were 289, 3799, 1928, and 52.8% for those who received a prior dose of Menveo 3-6 years earlier (N=176). Seroresponse rates at Day 6 following booster dose with MenQuadfi were 86.2%, 89.1%, 97.8%, and 95.7% for serogroups A, C, W, and Y, respectively, in MenQuadfi-primed participants (N=46) and 77.6%, 93.3%, 89.9%, and 91.1% for serogroups A, C, W, and Y, respectively. In Menveo-primed participants (N=45).

Following a booster dose of MenQuadfi, the hSBA GMTs at Day 6 were 289, 3799, 1928, and 52.8% for those who received a prior dose of Menveo 3-6 years earlier (N=176). Seroresponse rates at Day 6 following booster dose with MenQuadfi were 86.2%, 89.1%, 97.8%, and 95.7% for serogroups A, C, W, and Y, respectively. In MenQuadfi-primed participants (N=46) and 77.6%, 93.3%, 89.9%, and 91.1% for serogroups A, C, W, and Y, respectively. In Menveo-primed participants (N=45). Following a booster dose of MenQuadfi, the hSBA GMTs at Day 6 were 289, 3799, 1928, and 52.8% for those who received a prior dose of Menveo 3-6 years earlier (N=176).

### Table 11: Comparison of hSBA Seroresponse Rates 30 Days Following Booster Vaccination with MenQuadfi in Participants 13 through 26 Years of Age Primed with MenQuadfi or Menveo 3-6 Years Previously (Study 6)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>MenQuadfi-primed (95% CI)</th>
<th>Menveo-primed (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>94.8 (90.4; 97.6)</td>
<td>93.2 (88.4; 96.4)</td>
</tr>
<tr>
<td>C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>97.1 (93.4; 99.1)</td>
<td>98.9 (96.0; 99.9)</td>
</tr>
<tr>
<td>W</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>97.7 (94.2; 99.4)</td>
<td>98.9 (96.0; 99.9)</td>
</tr>
<tr>
<td>Y</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>98.9 (95.9; 99.9)</td>
<td>100 (97.9; 100)</td>
</tr>
</tbody>
</table>

N: number of subjects in Per-Protocol Analysis Set 2 (D30) with valid serology results. *Clinical trial identifier NCT04084769
†Seroresponse rate (primary endpoint) for each serogroup: 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.
‡The overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI was > -50%.
Table 12: Comparison of hSBA Seroresponse Rates 30 Days Following Vaccination with MenQuadfi in Participants ≥ 59 Years of Age Primed with MenQuadfi or Received a Prior Dose of Menomune At Least 3 Years Previously (Study 7)

<table>
<thead>
<tr>
<th>Endpoint by Serogroup</th>
<th>MenQuadfi-primed (95% CI)</th>
<th>Prior dose of Menomune (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>N=145 79.3 (71.8; 85.6)</td>
<td>N=130 60.8 (51.8; 69.2)</td>
</tr>
<tr>
<td>C</td>
<td>N=145 93.1 (87.7; 96.6)</td>
<td>N=130 55.0 (46.0; 63.8)</td>
</tr>
<tr>
<td>W</td>
<td>N=145 90.3 (84.3; 94.6)</td>
<td>N=130 49.2 (40.4; 58.1)</td>
</tr>
<tr>
<td>Y</td>
<td>N=145 92.4 (86.8; 96.2)</td>
<td>N=130 49.2 (40.4; 58.1)</td>
</tr>
</tbody>
</table>

N: number of subjects in Per-Protocol Analysis Set 1 (D30) with valid serology results.
*Clinical trial identifier NCT04142242
†Seroresponse rate (primary endpoint) for each serogroup: 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.

Sufficiency of hSBA seroresponse after MenQuadfi vaccination was demonstrated if the lower limit of the 2-sided 95% CI was >40%.

Seroresponse rates at Day 6 following vaccination with MenQuadfi were 36.2%, 77.6%, 70.7%, and 72.4% for serogroups A, C, W, and Y, respectively, in MenQuadfi-primed participants (N=58) and 8.1%, 8.1%, 6.5%, and 8.1% for serogroups A, C, W, and Y, respectively, in participants who received a prior dose of Menomune (N=62). Following vaccination with MenQuadfi, the hSBA GMTs at Day 6 were 44, 206, 118, and 151 for MenQuadfi-primed participants (N=58) and 13, 11, 10, and 11 for participants who received a prior dose of Menomune (N=62) for serogroups A, C, W, and Y, respectively. At D30, the hSBA GMTs were 162, 638, 419, and 566 for MenQuadfi-primed participants (N=145) and 57, 56, 31, and 41 for participants who received a prior dose of Menomune (N=130). Prior to MenQuadfi vaccination, the percentage of subjects with hSBA titers ≥1:8 for serogroups A, C, W, and Y were 64.8%, 73.8%, 66.9%, and 72.4% for those who received a prior dose of Menomune at least 3 years earlier (N=145), and 65.4%, 49.2%, 40.0%, and 41.5% for those who received a prior dose of Menomune at least 3 years earlier (N=130).

14.3 Immunogenicity of Concomitantly Administered Vaccines

Concomitant administration of MenQuadfi with Tdap and HPV in adolescents 10 through 17 years was evaluated in Study 2 (NCT02199691). In this randomized study, 503 participants received MenQuadfi alone, 392 received MenQuadfi coadministered with Tdap and HPV, 296 received Tdap and HPV alone. A fourth group received Menveo alone (N=501).

No evidence of interference in hSBA seroresponse rates was observed when MenQuadfi was coadministered with Tdap and HPV. Antibody responses to HPV, and to the tetanus and diphtheria antigens were similar when Tdap and HPV were administered with and without MenQuadfi. Anti-pertussis GMC responses were non-inferior for the pertussis toxoid antigen, but did not meet non-inferiority for the FHA, PRN, and FIM antigens. The clinical relevance of the diminished responses to the pertussis antigens is unknown.

16 HOW SUPPLIED/STORAGE AND HANDLING

MenQuadfi is supplied in a single-dose vial (NDC 49281-590-58):
in packages of 1 vial (NDC 49281-590-01);
in packages of 5 vials (NDC 49281-590-05);
in packages of 10 vials (NDC 49281-590-10).
Not all pack sizes may be marketed.
The vial stopper is not made with natural rubber latex.
Store at 2°C to 8°C (35°F to 46°F). Do not freeze. Do not use vaccine that has been frozen.
Do not use after expiration date.

17 PATIENT COUNSELING INFORMATION

Vaccine Information Statements are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization to the patient, parent, or guardian. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines). Inform the patients, parents or guardians about:

- Potential benefits and risks of immunization with MenQuadfi.
- Potential for adverse reactions that have been temporally associated with administration of MenQuadfi or other vaccines containing similar components.
- Reporting any adverse reactions to their healthcare provider.
- The Sanofi Pasteur Inc. Pregnancy Registry, as appropriate [see Pregnancy (8.1)].

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