MenQuadfi is a vaccine indicated for active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, W135. MenQuadfi is approved for use in individuals 2 years of age and older. (1) MenQuadfi does not prevent N. meningitidis serogroup B disease.

**DOSE 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 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.

**DOSE FORMS AND STRENGTHS**

Solution for injection in 0.5 mL single-dose vial. (3)

**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.

**8 USE IN SPECIFIC POPULATIONS**

8.1 Pregnancy
8.2 Lactation
8.4 Pediatric Use
8.5 Geriatric Use

**ADVERSE REACTIONS**

**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)

**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%)
- Adults 18 through 55 years, injection site pain (41.9%), myalgia (35.6%), and malaise (19.0%)
- Adults 56 years of age and older, injection site pain (35.5%), myalgia (21.9%), and malaise (14.5%)

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 1-800-822-7977 or www.vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION

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

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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.

### Primary Vaccination Studies

Children 2 through 9 years of age

The safety of MenQuadfi in children 2 through 9 years of age was evaluated in Study 1 (NCT03077438). The safety analysis set included 498 participants who received MenQuadfi and 494 participants who received Menveo [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine]. Of the participants 2 through 9 years of age who received MenQuadfi (N = 498), 50.2% were 2 through 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.

### 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></td>
<td></td>
</tr>
<tr>
<td>Injection Site Pain²</td>
<td>38.6 0.6</td>
<td>42.4 1.0</td>
</tr>
<tr>
<td>Injection Site Erythema³</td>
<td>22.6 3.1</td>
<td>31.5 9.9</td>
</tr>
<tr>
<td>Injection Site Swelling³</td>
<td>13.8 1.4</td>
<td>21.5 5.6</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia³</td>
<td>20.1 0.4</td>
<td>23.0 0.8</td>
</tr>
<tr>
<td>Malaise³</td>
<td>21.1 1.8</td>
<td>20.4 1.0</td>
</tr>
<tr>
<td>Headache³</td>
<td>12.5 0.0</td>
<td>11.5 0.4</td>
</tr>
<tr>
<td>Fever³</td>
<td>1.9 0.0</td>
<td>2.7 0.4</td>
</tr>
</tbody>
</table>

*Clinical trial identifier NCT03077438

†N is the number of vaccinated participants with available data for the events listed

‡Grade 3: Unable to perform usual activities

§Grade 3: Prevents daily activity

¶Any: > 0 mm; Grade 3: > 50 mm

¶Any: > 100 mm; Grade 3: > 200 mm

### 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 (NCT020842853). 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) Poly saccharide Diphtheria Toxoid Conjugate Vaccine] (323 participants).

Of the participants 10 through 17 years of age who received MenQuadfi (N = 1,684), 49.6% were female. Among those with reported race and ethnicity, 73.3% were White, 14.2% were Black or African American, 1.1% were Asian, 5.4% were of other racial groups, and 22.9% 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 0.6% 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 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>Adverse Reactions</th>
<th>MenQuadfi (N=494-496) %</th>
<th>Menveo (N=488-491) %</th>
<th>MenQuadfi (N=1129-1159) %</th>
<th>Menactra (N=310-314) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Site Pain³</td>
<td>45.2 1.4</td>
<td>42.5 1.0</td>
<td>34.8 1.8</td>
<td>41.4 2.2</td>
</tr>
<tr>
<td>Injection Site Erythema³</td>
<td>5.0 0.4</td>
<td>7.5 1.2</td>
<td>4.5 0.3</td>
<td>4.5 0.3</td>
</tr>
<tr>
<td>Injection Site Swelling³</td>
<td>5.4 0.2</td>
<td>6.5 0.4</td>
<td>4.1 0.1</td>
<td>4.8 0.0</td>
</tr>
<tr>
<td>Systemic Reactions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia³</td>
<td>35.3 1.6</td>
<td>35.2 1.8</td>
<td>27.4 1.9</td>
<td>31.2 1.9</td>
</tr>
<tr>
<td>Headache³</td>
<td>30.2 1.8</td>
<td>30.9 1.8</td>
<td>26.5 2.3</td>
<td>28.0 1.9</td>
</tr>
<tr>
<td>Malaise³</td>
<td>26.0 2.2</td>
<td>26.4 2.8</td>
<td>19.4 1.2</td>
<td>23.9 1.3</td>
</tr>
<tr>
<td>Fever³</td>
<td>1.4 0.4</td>
<td>1.2 0.6</td>
<td>0.7 0.2</td>
<td>0.6 0.0</td>
</tr>
</tbody>
</table>

*Clinical trial identifier NCT02199691

†N is the number of vaccinated participants with available data for the events listed

‡N is the number of vaccinated participants with available data for the events listed

§Grade 3: Prevents daily activity

¶Any: > 100 mm; Grade 3: > 200 mm

¶Any: > 100°F (38.0°C); Grade 3: > 102.1°F (39.0°C)

Among 236 participants who received Tdap and HPV concomitantly (without MenQuadfi) and 392 participants who received MenQuadfi concomitantly 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 Menveo in Study 2 (NCT02199691) and 2 (0.2%) participants who received MenQuadfi in Study 3 (NCT020842853). Three 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.

Adults 18 through 55 years of age

The safety of MenQuadfi in adults 18 through 55 years of age was evaluated in Study 3 (NCT020842853). The safety analysis set included 1,495 participants who received MenQuadfi and 312 participants who received Menactra. Of the participants 18 years 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. The rates and severity of the solicited adverse reactions that occurred within 7 days following MenQuadfi compared with Menactra are presented in Table 3. Dizziness within 30 minutes following vaccination was experienced by 5 (0.3%) participants who received MenQuadfi and 1 (0.3%) participant who received Menactra. These events were non-serious and spontaneously resolved on the same day.

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 18 through 55 Years of Age (Study 3)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi (N=2,411-1,460) %</th>
<th>Menactra (N=2,973-3,01) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Site Pain²</td>
<td>41.9 1.9</td>
<td>35.0 1.3</td>
</tr>
<tr>
<td>Injection Site Erythema³</td>
<td>5.1 0.3</td>
<td>3.7 0.3</td>
</tr>
<tr>
<td>Injection Site Swelling³</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>Myalgia³</td>
<td>35.6 3.6</td>
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</tbody>
</table>
Table 3: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Vaccination with MenQuadfi or Menomence in Individuals 18 through 55 Years of Age (Study 3) (continued)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi (N=414-1,460) %</th>
<th>Menomence (N=297-301) %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Malaise</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical trial identifer NCT028428686 *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>22.9</td>
<td>18.9</td>
</tr>
<tr>
<td>Grade 3</td>
<td>2.9</td>
<td>3.3</td>
</tr>
<tr>
<td><strong>Fever</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>1.4</td>
<td>1.7</td>
</tr>
<tr>
<td>Grade 3</td>
<td>0.1</td>
<td>0.7</td>
</tr>
</tbody>
</table>

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†Solicited and graded by the investigator as possibly, probably, or definitely related to vaccination.
§Any: ≥ 25 mm; Grade 3: ≥ 100 mm
$25 mm; Grade 3: ≥ 102.1°F (39.0°C)
¶Grade 3: ≥ 100.4°F (38.0°C)
§Any: ≥ 100.4°F (38.0°C)
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Table 4: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Vaccination with MenQuadfi or Menomence in Individuals 56 Years of Age and Older Study 4

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi (N=436-443) %</th>
<th>Menomence (N=449-451) %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection Site Pain ($)</td>
<td>25.5</td>
<td>9.6</td>
</tr>
<tr>
<td>Injection Site Pain §§</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Injection Site Erythema ($)</td>
<td>5.2</td>
<td>0.0</td>
</tr>
<tr>
<td>Injection Site Erythema §§</td>
<td>0.2</td>
<td>0.0</td>
</tr>
<tr>
<td>Injection Site Swelling ($)</td>
<td>4.5</td>
<td>0.0</td>
</tr>
<tr>
<td>Injection Site Swelling §§</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
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<td></td>
<td></td>
</tr>
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<td>15.3</td>
</tr>
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<td>1.3</td>
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<tr>
<td>Headache ($)</td>
<td>19.0</td>
<td>14.6</td>
</tr>
<tr>
<td>Headache §§</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Malaise ($)</td>
<td>14.5</td>
<td>11.3</td>
</tr>
<tr>
<td>Malaise §§</td>
<td>1.4</td>
<td>1.8</td>
</tr>
<tr>
<td>Fever ($)</td>
<td>2.1</td>
<td>0.4</td>
</tr>
<tr>
<td>Fever §§</td>
<td>0.2</td>
<td>0.0</td>
</tr>
</tbody>
</table>

*Clinical trial identifer NCT028428686
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§Any: ≥ 25 mm; Grade 3: ≥ 100 mm
$25 mm; Grade 3: ≥ 102.1°F (39.0°C)

Booster Vaccination Study

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 Asian and 2.2% were of other racial groups, and 15.7% were of Hispanic or Latino ethnicity. The most commonly reported solicited adverse reactions were injection site pain (44.7%) and 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. The safety analysis set included 448 participants who received MenQuadfi intramuscularly and 453 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). 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 Menomence in Individuals 18 through 55 Years of Age (Study 3) (continued)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi (N=414-1,460) %</th>
<th>Menomence (N=297-301) %</th>
</tr>
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<tbody>
<tr>
<td><strong>Malaise</strong></td>
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</tr>
<tr>
<td>Clinical trial identifer NCT028428686 *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>22.9</td>
<td>18.9</td>
</tr>
<tr>
<td>Grade 3</td>
<td>2.9</td>
<td>3.3</td>
</tr>
<tr>
<td><strong>Fever</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any</td>
<td>1.4</td>
<td>1.7</td>
</tr>
<tr>
<td>Grade 3</td>
<td>0.1</td>
<td>0.7</td>
</tr>
</tbody>
</table>

*Clinical trial identifer NCT028428686
†Solicited and graded by the investigator as possibly, probably, or definitely related to vaccination.
§Any: ≥ 25 mm; Grade 3: ≥ 100 mm
$25 mm; Grade 3: ≥ 102.1°F (39.0°C)

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

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>MenQuadfi (N=436-443) %</th>
<th>Menomence (N=449-451) %</th>
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<tbody>
<tr>
<td><strong>Local Reactions</strong></td>
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<td></td>
</tr>
<tr>
<td>Injection Site Pain ($)</td>
<td>25.5</td>
<td>9.6</td>
</tr>
<tr>
<td>Injection Site Pain §§</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Injection Site Erythema ($)</td>
<td>5.2</td>
<td>0.0</td>
</tr>
<tr>
<td>Injection Site Erythema §§</td>
<td>0.2</td>
<td>0.0</td>
</tr>
<tr>
<td>Injection Site Swelling ($)</td>
<td>4.5</td>
<td>0.0</td>
</tr>
<tr>
<td>Injection Site Swelling §§</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Systemic Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaise ($)</td>
<td>21.9</td>
<td>15.3</td>
</tr>
<tr>
<td>Malaise §§</td>
<td>1.6</td>
<td>1.3</td>
</tr>
<tr>
<td>Headache ($)</td>
<td>19.0</td>
<td>14.6</td>
</tr>
<tr>
<td>Headache §§</td>
<td>0.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Malaise ($)</td>
<td>14.5</td>
<td>11.3</td>
</tr>
<tr>
<td>Malaise §§</td>
<td>1.4</td>
<td>1.8</td>
</tr>
<tr>
<td>Fever ($)</td>
<td>2.1</td>
<td>0.4</td>
</tr>
<tr>
<td>Fever §§</td>
<td>0.2</td>
<td>0.0</td>
</tr>
</tbody>
</table>

*Clinical trial identifer NCT028428686
†Solicited and graded by the investigator as possibly, probably, or definitely related to vaccination.
§Any: ≥ 25 mm; Grade 3: ≥ 100 mm
$25 mm; Grade 3: ≥ 102.1°F (39.0°C)

Booster Vaccination Study

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 Asian and 2.2% were of other racial groups, and 15.7% were of Hispanic or Latino ethnicity. The most commonly reported solicited adverse reactions were injection site pain (44.7%) and 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 4.6%, 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.

8 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)].
to measure antibodies with hSBA. The hSBA geometric mean titers (GMTs) and proportion of participants who achieved hSBA seroresponse (defined below) were evaluated.

- Seroresponse rate 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.

Non-inferiority of MenQuadfi seroresponse rates versus those for comparator vaccines was demonstrated for all 4 serogroups in individuals 2 years of age and older who received a primary vaccination in individuals 15 years of age and older who received a booster vaccination at least 4 years following a previous dose of a meningococcal (groups A, C, W, Y) conjugate vaccine.

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 seroresponse rate and GMTs are presented in Table 5.

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

**Immunogenicity in Adolescents 10 through 17 Years of Age**

Immunogeneity 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 male and female participants and evaluated seroresponses 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 6.

Table 6: Comparison of Bactericidal Antibody Responses to MenQuadfi and Menveo 30 Days after Vaccination of Participants 10 through 17 Years of Age Study 2

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>MenQuadfi (95% CI)</th>
<th>Menveo (95% CI)</th>
<th>Percent difference MenQuadfi minus Menveo† (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>N=463</td>
<td>N=464</td>
<td>9.8 (3.7; 15.9)</td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>70.2 (65.6; 74.3)</td>
<td>60.3 (55.7; 64.8)</td>
<td></td>
</tr>
<tr>
<td>GMT</td>
<td>44 (39; 50)</td>
<td>35 (30; 41)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>N=462</td>
<td>N=463</td>
<td>34.5 (29.7; 39.3)</td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>96.1 (93.9, 97.7)</td>
<td>61.6 (57.0, 66.0)</td>
<td></td>
</tr>
<tr>
<td>GMT</td>
<td>387 (263; 456)</td>
<td>51 (41; 64)</td>
<td></td>
</tr>
</tbody>
</table>

Days after Vaccination of Participants 2 through 9 Years of Age (Study 1)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>MenQuadfi (95% CI)</th>
<th>Menveo (95% CI)</th>
<th>Percent difference MenQuadfi minus Menveo† (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>N=455-456</td>
<td>N=458</td>
<td>7.6 (1.1, 14.0)</td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>55.4 (50.7; 60.0)</td>
<td>47.8 (43.2; 52.5)</td>
<td></td>
</tr>
<tr>
<td>GMT</td>
<td>25 (22; 28)</td>
<td>23 (20; 26)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>N=458</td>
<td>N=458-459</td>
<td>47.4 (42.2, 52.2)</td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>95.2 (92.8; 97.0)</td>
<td>47.8 (43.2; 52.5)</td>
<td></td>
</tr>
<tr>
<td>GMT</td>
<td>238 (209; 270)</td>
<td>17.0 (14; 20)</td>
<td></td>
</tr>
<tr>
<td>W</td>
<td>N=458</td>
<td>N=459</td>
<td>14.8 (8.9, 20.5)</td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>78.8 (74.8; 82.5)</td>
<td>64.1 (59.5; 68.4)</td>
<td></td>
</tr>
<tr>
<td>GMT</td>
<td>38 (34; 42)</td>
<td>26 (23; 30)</td>
<td></td>
</tr>
<tr>
<td>Y</td>
<td>N=458</td>
<td>N=459</td>
<td>12.2 (7.7, 16.7)</td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>91.5 (88.5; 93.9)</td>
<td>79.3 (75.3; 82.9)</td>
<td></td>
</tr>
<tr>
<td>GMT</td>
<td>69 (61; 77)</td>
<td>44 (38; 50)</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 NCT03077438
†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.

Study 3 evaluated the immunogenicity of MenQuadfi (N=1997-1098) 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 noninferiority 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 (NCT02342653). The hSBA seroresponse rate and GMTs are presented in Table 7.

Immunune non-inferiority, based on seroresponse rates, was demonstrated for MenQuadfi as compared to Menactra for all four serogroups.

**Immunogenicity in Adolescents 10 through 17 Years of Age**

Immunogeneity of MenQuadfi compared to Menveo in participants 10 through 17 years of age was evaluated in Study 3 (NCT02199691). Study 2 was conducted in healthy meningococcal vaccine naïve participants and evaluated seroresponses 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 6.

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

Table 7: Comparison of Bactericidal Antibody Responses to MenQuadfi and Menactra 30 Days after Vaccination of Participants 18 through 55 Years of Age Study 3

<table>
<thead>
<tr>
<th>Endpoint†</th>
<th>MenQuadfi (95% CI)</th>
<th>Menactra (95% CI)</th>
<th>Percent difference MenQuadfi minus Menactra‡ (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>N=1,406-1,408</td>
<td>N=293</td>
<td>19.6 (13.5; 25.8)</td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>73.5 (71.2; 75.8)</td>
<td>53.9 (48.0; 59.7)</td>
<td></td>
</tr>
<tr>
<td>GMT</td>
<td>106 (97; 117)</td>
<td>52 (43; 64)</td>
<td></td>
</tr>
</tbody>
</table>
The overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI is greater than the lower limit of the 2-sided 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.

95% CI of the single proportion calculated from the exact binomial method.

The hSBA seroresponse rate and GMT s are presented in Table 8.

Table 7: Comparison of Bactericidal Antibody Responses to MenQuadfi and Menactra 30 Days after Vaccination of Participants 18 through 55 Years of Age Study 3 (continued)

<table>
<thead>
<tr>
<th>Endpoint^1</th>
<th>MenQuadfi (95% CI)</th>
<th>Menactra (95% CI)</th>
<th>Percent difference MenQuadfi minus Menactra^2 (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>N=1,406-1,408</td>
<td>N=293</td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>83.4 (81.4, 85.3)</td>
<td>42.3 (36.6, 48.2)</td>
<td>41.1 (35.0, 46.9)</td>
</tr>
<tr>
<td>GMT</td>
<td>234 (210, 261)</td>
<td>37 (25, 49)</td>
<td></td>
</tr>
<tr>
<td>W</td>
<td>N=1,408-1,410</td>
<td>N=293</td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>77.0 (74.1, 79.2)</td>
<td>50.2 (44.3, 56.0)</td>
<td>26.8 (20.7, 32.9)</td>
</tr>
<tr>
<td>GMT</td>
<td>76 (69, 83)</td>
<td>33 (26, 42)</td>
<td></td>
</tr>
<tr>
<td>Y</td>
<td>N=1,408-1,410</td>
<td>N=293</td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>88.1 (86.3, 89.8)</td>
<td>60.8 (54.9, 66.4)</td>
<td>27.4 (21.7, 33.3)</td>
</tr>
<tr>
<td>GMT</td>
<td>219 (200, 239)</td>
<td>55 (42, 70)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endpoint^1</th>
<th>MenQuadfi (95% CI)</th>
<th>Menomune (95% CI)</th>
<th>Percent difference MenQuadfi minus Menomune^3 (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>N=433</td>
<td>N=431</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 (9.8, 22.2)</td>
</tr>
<tr>
<td>GMT</td>
<td>55 (47, 65)</td>
<td>31 (27, 37)</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>N=433</td>
<td>N=431</td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>77.1 (72.3, 81.0)</td>
<td>49.7 (44.6, 54.5)</td>
<td>27.5 (21.2, 33.5)</td>
</tr>
<tr>
<td>GMT</td>
<td>101 (84, 123)</td>
<td>25 (21, 30)</td>
<td></td>
</tr>
<tr>
<td>W</td>
<td>N=433</td>
<td>N=431</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 (24, 33)</td>
<td>15 (13, 18)</td>
<td></td>
</tr>
<tr>
<td>Y</td>
<td>N=433</td>
<td>N=431</td>
<td></td>
</tr>
<tr>
<td>% Participants achieving Seroresponse</td>
<td>74.4 (70.0, 79.4)</td>
<td>43.4 (36.7, 48.2)</td>
<td>31.0 (24.6, 37.0)</td>
</tr>
</tbody>
</table>

N: number of participants in per-protocol analysis set with valid serology results.

†95% CI of the difference calculated from the Wilson Score method without continuity correction.

‡95% CI of the single proportion calculated from the exact binomial method.

The 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

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

Table 8: 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^1</th>
<th>MenQuadfi (95% CI)</th>
<th>Menomune (95% CI)</th>
<th>Percent difference MenQuadfi minus Menomune^3 (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMT</td>
<td>69 (59, 81)</td>
<td>21 (17, 25)</td>
<td></td>
</tr>
</tbody>
</table>

N: number of participants in per-protocol analysis set with valid serology results.

†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

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 Menveo 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 Study.

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 Menveo or Menactra 4 to 10 years ago. Seroresponse was 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.

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

Table: 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^1</th>
<th>MenQuadfi (95% CI)</th>
<th>Menomune (95% CI)</th>
<th>Percent difference MenQuadfi minus Menomune^3 (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GMT</td>
<td>69 (59, 81)</td>
<td>21 (17, 25)</td>
<td></td>
</tr>
</tbody>
</table>

N: number of participants in per-protocol analysis set with valid serology results.

†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.

14.3 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 5 vials (NDC 49281-590-05). 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 parent, patient, 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 parents, patients 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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