HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Menomune® – A/C/Y/W-135 vaccine safely and effectively. See full prescribing information for Menomune® – A/C/Y/W-135 vaccine.

Menomune® – A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined Solution for subcutaneous injection

Initial U.S. Approval: 1981

—INDICATIONS AND USAGE—-

• Menomune – A/C/Y/W-135 vaccine is a vaccine indicated for active immunization against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y, and W-135. Menomune – A/C/Y/W-135 vaccine is approved for use in persons 2 years of age and older. Menomune – A/C/Y/W-135 vaccine does not prevent Neisseria meningitidis serogroup B disease. (1)

—DOSAGE AND ADMINISTRATION—-

• Single 0.5 mL subcutaneous injection. (2)

—DOSE FORMS AND STRENGTHS—-

• Menomune – A/C/Y/W-135 vaccine is supplied as a single dose or multidose (10 dose) vial of lyophilized vaccine, with corresponding single dose or multidose vial of diluent. After reconstitution of the lyophilized vaccine with the diluent, each dose consists of a 0.5 mL solution for injection. (3)

—CONTRAINDICATIONS—-

• Do not administer to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to Menomune – A/C/Y/W-135 vaccine or any component of the vaccine. (4)

—WARNINGS AND PRECAUTIONS—-

• The stoppers to the vials of lyophilized vaccine and diluent contain dry natural latex rubber that may cause allergic reactions. (5.1)

—ADVERSE REACTIONS—-

• Common (>10%) adverse events in children 2 to 10 years of age were injection site pain, drowsiness, irritability, and diarrhea. (6)

• Common (>10%) adverse events in persons 11 to 55 years of age were pain, redness, and induration at the injection site, headache, fatigue, malaise, arthralgia, and diarrhea. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc. at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or http://vaers.hhs.gov.

—DRUG INTERACTIONS—-

• Do not mix Menomune – A/C/Y/W-135 vaccine with other vaccines in the same syringe or vial. (7)

• Immunosuppressive therapies may reduce the immune response to Menomune – A/C/Y/W-135 vaccine. (7)

• No safety and immunogenicity data are available on the concomitant administration of Menomune – A/C/Y/W-135 vaccine with other US licensed vaccines. (7)

—USE IN SPECIFIC POPULATIONS—-

• Pregnancy: No human or animal data. Use only if clearly needed. (8.1)

• Geriatrics: Not known whether persons aged 65 years and older respond differently from younger persons. (8.5)

See 17 for Patient Counseling Information.

Revised: [April 2013]

FULL PRESCRIBING INFORMATION: CONTENTS*

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2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
  8.1 Pregnancy
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11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
13 NON-CLINICAL TOXICOLOGY
13.1 Carcinogenesis, mutagenesis, impairment of fertility
14 CLINICAL STUDIES
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
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*Sections or subsections omitted from the full prescribing information are not listed.
FULL PRESCRIBING INFORMATION:
1. INDICATIONS AND USAGE

2. DOSAGE AND ADMINISTRATION
2.1. Administration
The vaccine contains a vial of lyophilized vaccine and a vial of diluent. The lyophilized vaccine should be a white or off-white color to a light beige color. The diluent used for reconstitution is a clear, colorless liquid.

Using a suitable sterile needle and syringe and aseptic technique, withdraw the supplied diluent (0.6 mL for single dose presentation and 6.0 mL for multidose presentation) (Refer to Figure 1) and inject into the vial containing the lyophilized vaccine (Refer to Figure 2). Swirl the vial until the vaccine is thoroughly dissolved (Refer to Figure 3). When reconstituted, the vaccine should be a clear, colorless liquid.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

Using a suitable sterile needle and syringe and aseptic technique, withdraw (Refer to Figure 4) and administer a 0.5 mL dose of Menomune – AC/Y/C/W-135 vaccine by subcutaneous injection. Use a separate sterile needle and syringe and aseptic technique for each dose withdrawn from the multidose vial.

Do not administer this product intravenously or intramuscularly.

The preferred site of administration is the deltoid region.

Menomune vaccine: Instructions for reconstitution

Figure 1
For the single-dose presentation, withdraw 0.6 mL of the supplied diluent for the multidose presentation, withdraw 6.0 mL.

Figure 2
Insert the syringe needle through the stopper of the vial of lyophilized Menomune vaccine component and inject the diluent into the vial.

Figure 3
Swirl the vial until the lyophilized vaccine component is thoroughly dissolved.

Figure 4
After reconstitution, withdraw 0.5 mL of Menomune vaccine and administer subcutaneously. Use the single-dose presentation immediately after reconstitution. The multidose presentation may be used for up to 35 days after reconstitution if stored at 2 to 8°C.

The vaccine should not be combined through reconstitution or mixed with any other vaccine.

Vaccine supplied in single dose vials should be used immediately after reconstitution. Vaccine supplied in multidose vials may be used for up to 35 days after reconstitution if stored at 2 to 8°C (36 to 46°F). (See How Supplied/Storage and Handling (16.2)).

2.2. Primary Immunization
Primary immunization with Menomune – AC/Y/C/W-135 vaccine consists of a single 0.5 mL dose administered subcutaneously.
The ACIP (Advisory Committee on Immunization Practices) has specific recommendations for use of meningococcal vaccines. (1) (3) (6)

2.3. Revaccination
The ACIP has recommendations for revaccination against meningococcal disease for persons at high risk who were previously vaccinated with Menomune – AC/Y/C/W-135 vaccine. (1) (3) (6)

3. DOSAGE FORMS AND STRENGTHS
Menomune – AC/Y/C/W-135 vaccine is supplied as a lyophilized vaccine, in a single dose or a multidose vial, with corresponding single dose or multidose vial of diluent. The lyophilized vaccine is reconstituted with the diluent [see Dosage and Administration (2.1)]. After reconstitution, each dose consists of a 0.5 mL solution for injection. See Description (11) for the complete listing of ingredients.

4. CONTRAINDICATIONS
4.1. Hypersensitivity
Do not administer to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to Menomune – AC/Y/C/W-135 vaccine or any component of the vaccine [see Description (11)].

5. WARNINGS AND PRECAUTIONS
5.1. Latex
The stoppers to the vials of lyophilized vaccine and diluent contain dry natural latex rubber that may cause allergic reactions in latex-sensitive persons.

5.2. Management of Acute Allergic Reactions
Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.3. Moderate or Severe Acute Illness
To avoid diagnostic confusion between manifestations of an acute illness and possible vaccine adverse effects, vaccination with Menomune – AC/Y/C/W-135 vaccine should be postponed in persons with moderate or severe acute illness. (4)

5.4. Limitations of Vaccine Effectiveness
Menomune – AC/Y/C/W-135 vaccine may not protect all recipients.

5.5. Altered Immunocompetence
Persons who are immunosuppressed, including persons receiving immunosuppressive therapy, may have a diminished immune response to Menomune AC/Y/C/W-135 vaccine [see Drug Interactions (7)].

6. ADVERSE REACTIONS
6.1. Data from Clinical Studies
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in clinical practice.

In three clinical trials primarily designed to assess the safety and immunogenicity of another vaccine, Menactra® (Meningococcal [Groups A, C, Y, and W-135] Polysaccharide Conjugate Vaccine), participants were randomized to receive Menactra or Menomune – AC/Y/C/W-135 vaccine, which was used as a control vaccine. In these three trials, 1519 children 2-10 years of age, 972 persons 11-18 years of age, and 1170 adults 18-55 years of age, respectively, received a dose of Menomune – AC/Y/C/W-135 vaccine. Overall, of the children 2-10 years of age who received Menactra or Menomune – AC/Y/C/W-135 vaccine, 68% were enrolled at US sites and 32% were enrolled at a Chilean site. The median ages of US and Chilean children were 6 and 5 years, respectively; overall, 50.5% were males and 49.5% were Caucasian. Among participants 11-55 years of age who received Menactra or Menomune – AC/Y/C/W-135 vaccine, all were enrolled at US sites; 54.8% were female; 97.7% were Caucasian.

Solicited local and systemic reactions were monitored daily for 7 days post-vaccination using a diary card. Information on serious adverse events was collected at interim clinic visits and by telephone interview conducted 6 months post-vaccination. At least 94% of participants from the three studies completed the 6-month follow-up.

Serious Adverse Events
Across the three studies, serious adverse events within 6 months following Menomune – AC/Y/C/W-135 vaccine were reported in 0.7% of 1519 children 2-10 years of age, 0.6% of 972 persons 11-18 years of age, and 1.7% of 1170 persons 18-55 years of age.

Solicited Adverse Events
The most commonly reported solicited adverse events in US children 2-10 years of age were injection site pain, irritability, and headache. (Table 1).
The most commonly reported solicited adverse events in adolescents, ages 11-18 years, and adults, ages 18-55 years, were injection site pain, headache, and fatigue. (Table 2).

Table 1: Percentage of US Participants 2-10 Years of Age Reporting Solicited Adverse Events Within 7 Days Following Administration of Menomune – AC/Y/C/W-135 Vaccine

<table>
<thead>
<tr>
<th>Event</th>
<th>Any</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>General disorders and administration site conditions</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Pain‡</td>
<td>26.1</td>
<td>2.5</td>
<td>0.0</td>
</tr>
<tr>
<td>Redness†</td>
<td>7.9</td>
<td>0.5</td>
<td>0.0</td>
</tr>
<tr>
<td>Induration‡</td>
<td>4.2</td>
<td>0.6</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling‡</td>
<td>2.8</td>
<td>0.3</td>
<td>0.0</td>
</tr>
<tr>
<td>Systemic events‡</td>
<td>5.2</td>
<td>1.7</td>
<td>0.2</td>
</tr>
<tr>
<td>Gastrintestinal disorders</td>
<td>8.7</td>
<td>1.3</td>
<td>0.8</td>
</tr>
<tr>
<td>Anorexia‡</td>
<td>2.7</td>
<td>0.7</td>
<td>0.6</td>
</tr>
<tr>
<td>Vomiting‡</td>
<td>11.8</td>
<td>2.5</td>
<td>0.3</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>11.2</td>
<td>2.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Irritability†</td>
<td>12.2</td>
<td>2.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Seuzures‡</td>
<td>0.0</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>5.3</td>
<td>0.7</td>
<td>0.0</td>
</tr>
<tr>
<td>Arthritis‡</td>
<td>3.0</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Skin and subcutaneous disorders</td>
<td>3.0</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

† N = The total number of participants with reported data. The N is 1027 for all solicited events except fever (N=1019). The percentage is based on N.
‡ Moderate: Discomforting, interfered with or limited usual arm movement, Severe: Disabling, child unable to move arm.
8. IMMUNORESPONSES TO MENOMUNE – A/C/Y/W-135 VACCINE

Immunosuppressive therapies may reduce the immune response to Menomune – A/C/Y/W-135 vaccine. No safety and immunogenicity data are available on the concomitant administration of Menomune – A/C/Y/W-135 vaccine with other US licensed vaccines.

8. USE IN SPECIFIC POPULATIONS

8.1. Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with Menomune – A/C/Y/W-135 vaccine. It is also not known whether Menomune – A/C/Y/W-135 vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Menomune – A/C/Y/W-135 vaccine should be given to a pregnant woman only if clearly needed.

8.3. Nursing Mothers

It is not known whether Menomune – A/C/Y/W-135 vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Menomune – A/C/Y/W-135 vaccine is administered to a nursing woman.

8.4. Pediatric Use

Safety and effectiveness of Menomune – A/C/Y/W-135 vaccine in children below the age of 2 years have not been established.

During a meningococcal serogroup A epidemic in sub-Saharan Africa, children 3 months to 16 years of age were vaccinated with a high molecular weight serogroup A meningococcal polysaccharide vaccine. In case-control studies, after 1 year of observation, vaccine efficacy against meningococcal serogroup A disease was estimated to be 87% (90% Confidence Interval (CI), 52% to 98%) overall. After 3 years, efficacy was estimated to be 67% (90% CI, 40% to 82%) among children who were 4-16 years of age at the time of vaccination and 5% (90% CI, 6% to 7%) among children who were 1-3 years of age at the time of vaccination (5).

The efficacy of a serogroup C meningococcal vaccine in infants and young children was evaluated in a placebo-controlled trial of 7 serogroup C disease in Brazil. Vaccine efficacy was estimated to be 12% (95% CI, -55% to 62%) among children from 6 months to 3 years of age and 5% (95% CI, -4% to 7%) among children from 24 to 36 months of age. (6)

8.5. Geriatric Use

Clinical studies of Menomune – A/C/Y/W-135 vaccine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

11. DESCRIPTION

Menomune – A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined, is a vaccine for subcutaneous injection. Menomune – A/C/Y/W-135 vaccine consists of a sterile lyophilized preparation of the group-specific meningococcal polysaccharides from antigens N, meningitidis Group A, Group C, Group Y, and Group W-135. N meningitidis are cultivated on Mueller Hinton casen agar (7) and grown in Watson Scherp casamino acid media (8). The purified polysaccharide is extracted from the N meningitidis cells and separated from the media by procedures which include centrifugation, detergents, alcohol precipitation, solvent or organic extraction, and diafiltration. No preservative is added during manufacture.

The diluent (0.6 mL) for the single dose presentation contains sterile, pyrogen-free distilled water without preservative. The diluent (6 mL) for the multidose presentation contains sterile, pyrogen-free distilled water and thimerosal, a mercapturic acid derivative, which is added as a preservative for the reconstituted vaccine. [See How Supplied/Storage and Handling (16)]. After reconstitution with diluent, the vaccine is a clear colorless liquid solution. Each 0.5 mL dose contains 50 mcg of polysaccharide from each of serogroups A, C, Y, and W-135. Reconstituted vaccine from a multidose vile also contains 25 mcg mercury per dose.

Each dose of vaccine contains 2.5 mg to 5 mg of lactose added as a stabilizer (9). Serum Potency is evaluated by measuring the molecular size of each polysaccharide component using a column chromatography method as standardized by the US Food and Drug Administration (FDA) and the World Health Organization (WHO) for the polysaccharide meningococcal vaccine.

12. CLINICAL PHARMACOLOGY

12.1. Mechanism of Action

The presence of bactericidal anti-capsular meningococcal antibodies has been associated with protection from invasive meningococcal disease. (11) (12) Menomune – A/C/Y/W-135 vaccine induces the production of bactericidal antibodies specific to the capsular polysaccharides of serogroups A, C, Y, and W-135.

13. NON-CLINICAL TOXICOLOGY

13.1. Carcinogenesis, impairment of fertility

Menomune – A/C/Y/W-135 vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

14. CLINICAL STUDIES

Effectiveness of Menomune – A/C/Y/W-135 vaccine was inferred by evaluating the proportion of children 2-10 years of age achieving a 4-fold increase from baseline in serum bactericidal antibody, for each serogroup. Evidence for clinical efficacy against serogroup-specific meningococcal disease in school-age children and adults has been obtained from field trial and observational studies with other high molecular weight polysaccharide vaccines containing meningococcal serogroup A and/or C components. (6) No studies have been conducted to evaluate the efficacy of meningococcal polysaccharide vaccines against disease due to serogroups Y and W-135.

Menomune – A/C/Y/W-135 vaccine was used as the control vaccine in three US, multicenter, clinical trials designed primarily to evaluate the immunogenicity and safety of Menactra vaccine in children (2-10 years old), adolescents (11-19 years old), and adults.

Table 2: Percentage of Participants 11-55 Years of Age Reporting Solicited Adverse Events Within 7 Days Following Administration of Menomune – A/C/Y/W-135 Vaccine

<table>
<thead>
<tr>
<th>Event</th>
<th>Study 1 N=970</th>
<th>Participants 11-18 years of age</th>
<th>Participants 18-55 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Moderate</td>
<td>Severe</td>
<td>Any Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injection site reaction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain†</td>
<td>28.7</td>
<td>25.6</td>
<td>0.0</td>
</tr>
<tr>
<td>Redness‡</td>
<td>5.7</td>
<td>4.4</td>
<td>0.7</td>
</tr>
<tr>
<td>Induration¶</td>
<td>5.2</td>
<td>5.2</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling§</td>
<td>3.6</td>
<td>3.6</td>
<td>0.0</td>
</tr>
<tr>
<td>Systemic events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue‖</td>
<td>25.1</td>
<td>22.6</td>
<td>2.2</td>
</tr>
<tr>
<td>Malaise‖</td>
<td>16.8</td>
<td>16.8</td>
<td>0.4</td>
</tr>
<tr>
<td>Child‖</td>
<td>3.5</td>
<td>3.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Fever¶</td>
<td>3.0</td>
<td>3.0</td>
<td>0.3</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea¶</td>
<td>16.2</td>
<td>16.2</td>
<td>1.3</td>
</tr>
<tr>
<td>Abdominal pain‡</td>
<td>7.7</td>
<td>7.7</td>
<td>1.1</td>
</tr>
<tr>
<td>Vomiting‖</td>
<td>1.4</td>
<td>1.4</td>
<td>0.5</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache‖</td>
<td>29.3</td>
<td>29.3</td>
<td>0.5</td>
</tr>
<tr>
<td>Seizure‖</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthralgia‖</td>
<td>16.2</td>
<td>16.2</td>
<td>2.1</td>
</tr>
<tr>
<td>Skin and subcutaneous disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash¶</td>
<td>1.4</td>
<td>1.4</td>
<td>0.0</td>
</tr>
</tbody>
</table>

‡ Moderate: 1.0-2.0 inches; Severe: ≥2.0 inches.
§ Oral equivalent temperature. Study 1: Moderate: 38.5-39.4ºC, Severe: ≥39.5ºC.
¶ Moderate: 2 episodes, Severe: ≥3 episodes.
§§ Moderate: Decreased range of motion due to pain or disable, Severe: Unable to engage in play or interaction with others.
|| Moderate: 1-3 hours duration, Severe: ≥3 hours duration.
‡‡ These solicited adverse events were reported as present or absent only.
外: Moderate: Interferes with normal activities, Severe: disabling, unwilling to engage in play or interaction with others.

18-55 years of age

N  m eningitidis

Serogroup

A
C
Y
W-135

Data on immunization effectiveness of Menomune – A/C/Y/W-135 vaccine in children below the age of 2 years have not been established.

Table 3: Bactericidal Antibody Responses for Children 11-18 Years of Age

<table>
<thead>
<tr>
<th>Serogroup</th>
<th>Study 1 N=1343</th>
<th>Study 2 N=1354</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>C</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Y</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>W-135</td>
<td>4.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Study 1 N=1343</th>
<th>Study 2 N=1354</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menomune</td>
<td>4.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>

18-55 years of age

N  m eningitidis

Serogroup

A
C
Y
W-135

Data on immunization effectiveness of Menomune – A/C/Y/W-135 vaccine in children below the age of 2 years have not been established.

Table 4: Bactericidal Antibody Responses for Children 11-18 Years of Age

<table>
<thead>
<tr>
<th>Serogroup</th>
<th>Study 1 N=1343</th>
<th>Study 2 N=1354</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>C</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Y</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>W-135</td>
<td>4.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Study 1 N=1343</th>
<th>Study 2 N=1354</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menomune</td>
<td>4.0</td>
<td>4.0</td>
</tr>
</tbody>
</table>
Menomone – administration

The-Serum Bacillus Assay (SBA) used to
test sera contained an exogenous complement source that was human (SBA-H) or
when correlated to SBA-H, rabbit (SBA-Br). (13)

Data on immune responses, as measured by SBA-H, following Menomone –
ACY/WY-135 vaccine in a subset of children 2-10 years old are presented in Table 3.
Data on immune responses, as measured by SBA-Br, following Menomone –
ACY/WY-135 vaccine in adolescents and adults are presented in Table 4.

Table 3: Bacterial Antibody Responses to Menomone –ACY/WY-135 Vaccine 28 Days After Vaccination for Subsets of Participants Aged 2-3 and 4-10 Years

<table>
<thead>
<tr>
<th>Serogroup</th>
<th>Menomone –ACY/WY-135 Vaccine Aged 2-3 Years N=50-53</th>
<th>Menomone –ACY/WY-135 Vaccine Aged 4-10 Years N=84</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>% 24-fold rises</td>
<td>95% CI</td>
</tr>
<tr>
<td>A</td>
<td>21.8</td>
<td>64</td>
</tr>
<tr>
<td>GMI</td>
<td>10</td>
<td>7.12</td>
</tr>
<tr>
<td>C</td>
<td>31.8</td>
<td>36</td>
</tr>
<tr>
<td>GMI</td>
<td>11</td>
<td>15</td>
</tr>
<tr>
<td>Y</td>
<td>31.8</td>
<td>7.9</td>
</tr>
<tr>
<td>GMI</td>
<td>16</td>
<td>11.27</td>
</tr>
<tr>
<td>W-135</td>
<td>21.8</td>
<td>33</td>
</tr>
</tbody>
</table>

The study was designed to show the safety and immunogenicity of Menactra vaccine are
inferior to that of Menomone –ACY/WY-135 vaccine. The table shows the immune response in Menomone –ACY/WY-135 vaccine participants from this study.

* Serum Bacterial Assay with an exogenous human complement (SBA-H) source.
† N = Number of subset participants with at least one valid serology result at Day 0 and Day 28.
‡ The 95% CI for the Geometric Mean Titer (GMT) was calculated based on an
   approximation to the normal distribution.

In participants 2-3 years of age with undetectable pre-vaccination SBA titers (ie, <4
at Day 0), rates of seroconversion (defined as SBA titer ≥8 at Day 28) following Menomone –
ACY/WY-135 vaccine were 55%, serogroup A (n=16/29); 30%, serogroup C
(n=9/30); 57%, serogroup Y (n=17/30); 26%, serogroup W-135 (n=5/19).

In participants 4-10 years of age with undetectable pre-vaccination SBA titers (ie, <4
at Day 0), rates of seroconversion (defined as SBA titer ≥8 at Day 28) following Menomone –
ACY/WY-135 vaccine were 48%, serogroup A (n=10/21); 38%, serogroup C
(n=9/24); 84%, serogroup Y (n=38/45); 68%, serogroup W-135 (n=26/38).

Table 4: Bacterial Antibody Responses to Menomone –ACY/WY-135 Vaccine 28 Days After Vaccination for Participants Aged 11-18 and 18-55 Years

<table>
<thead>
<tr>
<th>Serogroup</th>
<th>Menomone –ACY/WY-135 Vaccine Aged 11-18 Years N=423</th>
<th>Menomone –ACY/WY-135 Vaccine Aged 18-55 Years N=1098</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>% 24-fold rises</td>
<td>95% CI</td>
</tr>
<tr>
<td>A</td>
<td>92.4</td>
<td>89.5</td>
</tr>
<tr>
<td>GMI</td>
<td>1426</td>
<td>290</td>
</tr>
<tr>
<td>C</td>
<td>88.7</td>
<td>85.2</td>
</tr>
<tr>
<td>GMI</td>
<td>1639</td>
<td>1406</td>
</tr>
<tr>
<td>Y</td>
<td>80.1</td>
<td>76.0</td>
</tr>
<tr>
<td>GMI</td>
<td>1228</td>
<td>1086</td>
</tr>
<tr>
<td>W-135</td>
<td>96.3</td>
<td>92.8</td>
</tr>
<tr>
<td>GMI</td>
<td>1548</td>
<td>1384</td>
</tr>
</tbody>
</table>

Both studies (11-18 and 18-55 years of age) were designed to show the safety
and immunogenicity of Menactra vaccine are inferior to that of Menomone –ACY/WY-135
vaccine. The table shows the immune response in Menomone –ACY/WY-135 vaccine participants from these studies.

* Serum Bacterial Assay with baby rabbit complement (SBA-Br).
† N = Number of participants with valid serology results at Day 0 and Day 28.
‡ The 95% CI for the GMT was calculated based on an approximation to the normal
distribution.
§ The proportion of subjects with a ≥24-fold rise from baseline in SBA-Br titer for
N meningitidis for each of the serogroups A, C, Y and W-135, 28 days following
vaccination with Menomone –ACY/WY-135 vaccine.

Manufactured by:
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Menomone –AC/WY-135 is a registered trademark of sanofi pasteur and its subsidiaries.