MenQuadfi®, Meningococcal (Groups A, C, Y, W) Conjugate Vaccine Solution for Intramuscular Injection **Rx Only**

Brief Summary of 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.

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 [*see Description (11) in the full prescribing information*].

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 [*see Clinical Pharmacology (12.1) in the full prescribing information*].

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.

5.4 Guillain-Barré 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 = 4517), a booster dose (N = 1119) 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.

Safety 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 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 CRM_{197} 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)*

	MenQuadfi (N†=484-487) %		Menveo (N†=479-486) %	
Adverse Reactions	**Any**	**Grade 3**	**Any**	**Grade 3**
Local Reactions				
Injection Site Pain‡	38.6	0.6	42.4	1.0
Injection Site Erythema§	22.6	3.1	31.5	9.9
Injection Site Swelling§	13.8	1.4	21.5	5.6
Systemic Reactions				
Myalgia¶	20.1	0.4	23.0	0.8
Malaise¶	21.1	1.8	20.4	1.0
Headache¶	12.5	0.0	11.5	0.4
Fever#	1.9	0.0	2.7	0.4

*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

§Any: > 0 mm; Grade 3: ≥ 50 mm

¶Grade 3: Prevents daily activity

#Any: ≥ 100.4°F (38.0°C); Grade 3: ≥ 102.1°F (39.0°C)

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), 49.6% 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 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)†

	Study 2				Study 3			
	MenQuadfi (N‡=494-496) %		Menveo (N‡=488-491) %		MenQuadfi (N‡=1129-1159) %		Menactra (N‡=310-314) %	
Adverse Reactions	**Any**	**Grade 3**	**Any**	**Grade 3**	**Any**	**Grade 3**	**Any**	**Grade 3**
Local Reactions								
Injection Site Pain§	45.2	1.4	42.5	1.0	34.8	1.8	41.4	2.2
Injection Site Erythema¶	5.0	0.4	7.5	1.2	4.5	0.3	4.5	0.3
Injection Site Swelling¶	5.4	0.2	6.5	0.4	4.1	<0.1	4.8	0.0
Systemic Reactions								
Myalgia§	35.3	1.6	35.2	1.8	27.4	1.9	31.2	1.9
Headache§	30.2	1.8	30.9	1.8	26.5	2.3	28.0	1.9
Malaise§	26.0	2.2	26.4	2.8	19.4	1.2	23.9	1.3
Fever#	1.4	0.4	1.2	0.6	0.7	0.2	0.6	0.0

*Clinical trial identifier NCT02199691

†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)

Among 296 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 MenQuadfi in Study 2 (NCT02199691) and 2 (0.2%) participants who received MenQuadfi in Study 3 (NCT02842853). 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 (NCT02842853). 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)*

	MenQuadfi (N†=1,441-1,460) %		Menactra (N†=297-301) %	
Adverse Reactions	**Any**	**Grade 3**	**Any**	**Grade 3**
Local Reactions				
Injection Site Pain‡	41.9	1.9	35.0	1.3
Injection Site Erythema§	5.1	0.3	3.7	0.3
Injection Site Swelling§	4.3	0.2	3.4	0.3
Systemic Reactions				
Myalgia‡	35.6	3.6	31.2	2.3
Headache‡	29.0	2.9	27.6	2.7
Malaise‡	22.9	2.9	18.9	3.3
Fever¶	1.4	0.1	1.7	0.7

*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/Y/W-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 7.8% were of Hispanic or Latino ethnicity. Mean age was 67.0 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)*

	MenQuadfi (N†=436-443) %		Menomune‡ (N†=449-451) %	
Adverse Reactions	**Any**	**Grade 3**	**Any**	**Grade 3**
Local Reactions				
Injection Site Pain§	25.5	0.7	9.6	0.7
Injection Site Erythema¶	5.2	0.2	0.0	0.0
Injection Site Swelling¶	4.5	0.0	0.0	0.0
Systemic Reactions				
Myalgia§	21.9	1.6	15.3	1.3
Headache§	19.0	0.7	14.6	0.7

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)* (continued)

	MenQuadfi (N†=436-443) %		Menomune‡ (N†=449-451) %	
Adverse Reactions	**Any**	**Grade 3**	**Any**	**Grade 3**
Malaise§	14.5	1.4	11.3	1.8
Fever#	2.1	0.2	0.4	0.0

*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 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 (≥10%) within 7 days of MenQuadfi booster vaccination 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 4.0%, 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)*

	MenQuadfi in MenQuadfi-primed (N=186) %		MenQuadfi in Menveo-primed (N=184) %		MenQuadfi and Trumenba in MenQuadfi-primed (N=93) %		MenQuadfi and Bexsero in MenQuadfi-primed (N=92) %	
Adverse Reactions	**Any**	**Grade 3**	**Any**	**Grade 3**	**Any**	**Grade 3**	**Any**	**Grade 3**
Local Reactions†								
Injection Site Pain	38.2	0.5	33.7	1.1	48.9	5.4	56.5	0
Injection Site Erythema	6.5	0.5	5.4	0	1.1	0	6.5	1.1
Injection Site Swelling	5.4	0	1.6	0	2.2	0	5.4	1.1
Systemic Reactions								
Myalgia	32.8	1.6	34.8	1.1	65.2	7.6	63.0	4.3
Headache	36.0	1.1	34.8	1.6	42.4	4.3	39.1	2.2
Malaise	26.9	2.2	25.5	2.2	39.1	5.4	40.2	3.3
Fever	0	0	2.2	0.5	1.1	0	4.4	0

N: number of participants in the safety analysis set
*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 6.

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)*

	MenQuadfi-primed (N=162) %		Prior dose of Menomune (N=151) %	
Adverse Reactions	**Any**	**Grade 3**	**Any**	**Grade 3**
Local Reactions				
Injection Site Pain	16.7	0	21.2	0.7
Injection Site Erythema	3.7	0	7.3	0
Injection Site Swelling	3.7	0	4.6	0
Systemic Reactions				
Myalgia	21.6	2.5	19.9	1.3
Headache	18.5	0	13.9	0
Malaise	13.6	1.9	14.6	2.6
Fever	0.6	0	0	0

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) in the full prescribing information*].

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) in the full prescribing information*].

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) in the full prescribing information*].

MenQuadfi recipients ≥ 65 years of age had lower GMTs and seroresponse rates for all serogroups compared to MenQuadfi recipients 56 through 64 years of age [*see Clinical Studies (14.1) in the full prescribing information*].

Manufactured by:
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