COMPLETION IS THE KEY TO HELP PROTECT AGAINST MenB[1]

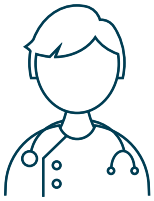
Trumenba®
Meningococcal Group B Vaccine

Take steps to help ensure protection from serogroup B meningococcal disease (MenB) with a full dose series of TRUMENBA

AT TIME OF FIRST DOSE:

1: Communicate the importance of dose series completion to patients and parents

After administering the first dose of TRUMENBA, emphasize the importance of completing the series to help provide protection against MenB.



↑ **41%**

Provider recommendation has been shown to improve vaccination coverage by as much as 41%[2]

2: Schedule your patients' next dose appointment

Prescheduling immunization appointments has been shown to improve vaccination rates.[3]

In a recent survey, patients with prescheduled flu vaccination appointments were up to 7 times more likely to get vaccinated[3]

3: Prompt patients to enroll in the REMEMBER TRUMENBA Program

Patients will receive text and/or email reminders about their next dose of TRUMENBA.

Patients can enroll at **RememberTRUMENBA.com** or by phone

Ask your representative for more details

AFTER FIRST DOSE:

4: Leverage EMR systems to run patient lists

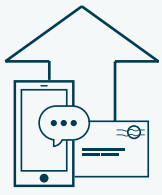
Regularly identify patients who are due or past due for their next dose of TRUMENBA and engage them in a timely manner.

6 MONTHS

TIP: Establish a routine of running patient lists 6 months after the back-to-school immunization period

5: Engage patients with reminder or recall communications

Including text messaging and postcard mailings in your outreach efforts has been shown to increase the likelihood of vaccination.[4]



TEXT: **39%**

POSTCARDS: **40%**

Percentage increase in likelihood to get vaccinated by channel[4]

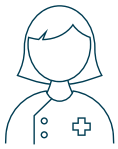
EMR, electronic medical records.

Take a team-based approach to maximize TRUMENBA dose series completion

Every staff member plays a role in helping to protect patients from MenB

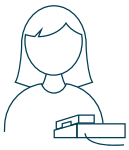
Physicians

- Discuss the importance of completing a full dose series of TRUMENBA with patients/parents
- Administer first dose or document vaccine refusal in EMR



Nurses

- Remind patients/parents to schedule a next dose appointment before leaving the office
- Help patients/parents enroll in the REMEMBER TRUMENBA Program



Office Staff

- Schedule next dose appointment
- Use EMR to identify patients who are due for next TRUMENBA dose and initiate reminder/recall outreach
- Ensure TRUMENBA is ordered and stocked at all times

Pfizer is committed to supporting your practice with resources to help improve TRUMENBA dose series completion.

Ask your representative about Pfizer support materials for your practice.

INDICATION

- Trumenba is a vaccine indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. Trumenba is approved for use in individuals 10 through 25 years of age
- The effectiveness of the two-dose schedule of Trumenba against diverse *N meningitidis* serogroup B strains has not been confirmed

IMPORTANT SAFETY INFORMATION

- Severe allergic reaction after a previous dose of Trumenba is a contraindication
- Individuals with altered immunocompetence may have reduced immune responses to Trumenba
- As with any vaccine, vaccination with Trumenba may not protect all vaccine recipients against *N meningitidis* serogroup B infections
- In clinical studies, the most common solicited adverse reactions in adolescents and young adults were pain at the injection site (≥85%), fatigue (≥60%), headache (≥55%), and muscle pain (≥35%). Nausea was reported in up to 24% of adolescents in early phase studies
- Sufficient data are not available on the safety and effectiveness of using Trumenba and other meningococcal group B vaccines interchangeably to complete the vaccination series
- Safety and effectiveness have not been established in pregnant women

Please see full Prescribing Information for TRUMENBA in the pocket.

References: 1. Trumenba [prescribing information]. Philadelphia, PA: Pfizer Inc; 2018. **2.** Dorell C, Yankey D, Kennedy A, et al. Factors that influence parental vaccination decisions for adolescents, 13 to 17 years old: National Immunization Survey-Teen, 2010. *Clin Pediatr (Phila).* 2013;52(2):162-170. **3.** Chapman GB, Li M, Leventhal H, et al. Default clinic appointments promote influenza vaccination uptake without a displacement effect. *Behavior Science & Policy.* 2016;2(2):41-50. **4.** Bar-Shain DS, Stager MM, Runkle AP, et al. Direct messaging to parents/guardians to improve adolescent immunizations. *J Adolesc Health.* 2015;56(5 Suppl):S21-S26.

Printed in USA/January 2018 PP-TRU-USA-1751

Trumenba®
Meningococcal Group B Vaccine

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use TRUMENBA safely and effectively. See full prescribing information for TRUMENBA.

TRUMENBA® (Meningococcal Group B Vaccine)
Suspension for intramuscular injection

Initial U.S. Approval: 2014

----------RECENT MAJOR CHANGES----------

Dosage and Administration, Dose and Schedule (2.1)	3/2017
Warnings and Precautions, Altered Immunocompetence (5.2)	3/2018
Warnings and Precautions, Limitation of Vaccine Effectiveness (5.3)	9/2017
Warnings and Precautions, syncope (5.4)	3/2018

----------INDICATIONS AND USAGE----------

- Trumenba is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. Trumenba is approved for use in individuals 10 through 25 years of age. (1)
- The effectiveness of the two-dose schedule of Trumenba against diverse *N. meningitidis* serogroup B strains has not been confirmed. (1)

----------DOSAGE AND ADMINISTRATION----------

- For intramuscular use only. (2)
- **Three-dose schedule:** Administer a dose (0.5 mL) at 0, 1-2, and 6 months. (2.1)
- **Two-dose schedule:** Administer a dose (0.5 mL) at 0 and 6 months. If the second dose is administered earlier than 6 months after the first dose, a third dose should be administered at least 4 months after the second dose. (2.1)

----------DOSAGE FORMS AND STRENGTHS----------

- Suspension for intramuscular injection in 0.5 mL single-dose prefilled syringe. (3)

----------CONTRAINDICATIONS----------

- Severe allergic reaction after a previous dose of Trumenba. (4)

----------WARNINGS AND PRECAUTIONS----------

Syncope (fainting) can occur in association with administration of injectable vaccines, including Trumenba. Procedures should be in place to avoid injury from fainting. (5.4)

----------ADVERSE REACTIONS----------

The most common solicited adverse reactions in adolescents and young adults were pain at the injection site (≥85%), fatigue (≥60%), headache (≥55%), and muscle pain (≥35%). (6)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer, Inc. at 1-800-438-1985 or VAERS at 1-800-822-7967 or http://vaers.hhs.gov.

----------USE IN SPECIFIC POPULATIONS----------

- **Pediatric Use:** Safety and effectiveness have not been established in children <10 years of age. In a clinical study, 90% of infants <12 months of age who were vaccinated with a reduced dosage formulation had fever. (8.4)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 3/2018

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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Trumenba is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. Trumenba is approved for use in individuals 10 through 25 years of age.

The effectiveness of the two-dose schedule of Trumenba against diverse *N. meningitidis* serogroup B strains has not been confirmed.

2 DOSAGE AND ADMINISTRATION

For intramuscular use only.

2.1 Dose and Schedule

Three-dose schedule: Administer a dose (0.5 mL) at 0, 1-2, and 6 months.

Two-dose schedule: Administer a dose (0.5 mL) at 0 and 6 months. If the second dose is administered earlier than 6 months after the first dose, a third dose should be administered at least 4 months after the second dose.

The choice of dosing schedule may depend on the risk of exposure and the patient's susceptibility to meningococcal serogroup B disease.

2.2 Administration

Shake syringe vigorously to ensure that a homogenous white suspension of Trumenba is obtained. Do not use the vaccine if it cannot be re-suspended. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if particulate matter or discoloration is found.

Inject each 0.5 mL dose intramuscularly, using a sterile needle attached to the supplied prefilled syringe. The preferred site for injection is the deltoid muscle of the upper arm. Do not mix Trumenba with any other vaccine in the same syringe.

2.3 Use of Trumenba with other Meningococcal Group B Vaccines

Sufficient data are not available on the safety and effectiveness of using Trumenba and other meningococcal group B vaccines interchangeably to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Trumenba is a suspension for intramuscular injection in 0.5 mL single-dose prefilled syringe.

4 CONTRAINDICATIONS

Severe allergic reaction after a previous dose of Trumenba.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Allergic Reactions

Epinephrine and other appropriate agents used to manage immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur following administration of Trumenba.

5.2 Altered Immunocompetence

Reduced Immune Response

Some individuals with altered immunocompetence may have reduced immune responses to Trumenba.

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* serogroup B even if they develop antibodies following vaccination with Trumenba *[see Clinical Pharmacology (12.0)]*.

5.3 Limitation of Vaccine Effectiveness

As with any vaccine, vaccination with Trumenba may not protect all vaccine recipients against *N. meningitidis* serogroup B infections.

5.4 Syncope

Syncope (fainting) can occur in association with administration of injectable vaccines, including Trumenba. Procedures should be in place to avoid injury from fainting.

6 ADVERSE REACTIONS

In clinical studies, the most common solicited adverse reactions in adolescents and young adults were pain at the injection site (≥85%), fatigue (≥60%), headache (≥55%),

and muscle pain (≥35%). Nausea was reported in up to 24% of adolescents in early phase studies.

6.1 Clinical Trials Experience

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.

The safety of Trumenba was evaluated in 15,227 subjects 10 through 25 years of age in 11 clinical studies (8 randomized controlled and 3 supportive non-controlled studies) conducted in the U.S., Europe, Canada, Chile, and Australia. A total of 11,333 adolescents (10 through 18 years of age) and 3,894 adults (19 through 25 years of age) received at least one dose of Trumenba. A total of 5,501 subjects 10 through 25 years of age in the control groups received saline placebo and/or one of the following vaccine(s): Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant (HPV4) (Merck & Co., Inc.); Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) (Sanofi Pasteur Ltd.); Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine (MCV4) (Sanofi Pasteur Inc.); a non-U.S. licensed reduced diphtheria toxoid, tetanus toxoid, acellular pertussis and inactivated polio virus vaccine (dTaP-IPV) (Sanofi Pasteur, Inc.); Hepatitis A Vaccine, Inactivated (HAV) (GlaxoSmithKline Biologicals).

The safety evaluation in the clinical studies included an assessment of: (1) solicited local and systemic reactions, and use of antipyretic medication after each vaccination in an electronic diary maintained by the subject or the subject's parent/legal guardian and (2) spontaneous reports of adverse events (AEs), including serious adverse events (SAEs), throughout the study (day of vaccination through one month or 6 months after the last vaccination, depending on the study and safety parameter).

In controlled studies, demographic characteristics were generally similar with regard to gender, race, and ethnicity among subjects who received Trumenba and those who received control. Overall, across the 11 studies, among the subjects who received Trumenba, 50.5% were male and 49.5% were female, and the majority were White (86.3%) and non-Hispanic/non-Latino (87.3%).

Solicited Local and Systemic Adverse Reactions

Study 1 was a Phase 3, randomized, active-controlled, observer-blinded, multicenter trial in the U.S., Canada, and Europe in which 2,693 subjects 10 to 18 years of age received at least 1 dose of Trumenba on a 0-, 2-, and 6- month schedule. A control group (n=897) received HAV at 0 and 6 months and saline at 2 months. 87.3% of subjects were White, 8.1% were Black or African-American, 0.4% were Asian, and 5.8% were Hispanic or Latino. Overall, 51.5% of subjects were male, 55.6% of participants were 10 to 14 years age, and 44.4% were 15 to 18 years of age.

Study 2 was a Phase 3, randomized, placebo-controlled, observer-blinded, multicenter trial in the U.S., Canada, and Europe in which 2,471 subjects 18 to 25 years of age received at least 1 dose of Trumenba and 822 subjects received saline on a 0-, 2,- and 6- month schedule. 76.1% of subjects were White, 20.8% were Black or African-American, 1.6% were Asian, and 17.1% were Hispanic or Latino. Overall, 41.3% of subjects were male.

Local adverse reactions at the Trumenba injection site and control (HAV/saline or saline) injection site were assessed in both studies.

Tables 1 and 2 present the percentage and severity of reported local adverse reactions within 7 days following each dose of Trumenba or control (HAV/saline or saline) for Study 1 and Study 2, respectively.

Local adverse reactions were reported more frequently following Trumenba compared to control (see Tables 1 and 2).

Table 1: Percentages of Subjects 10 to 18 Years of Age (Study 1[a]) Reporting Local Adverse Reactions Within 7 Days After Each Vaccination

	Dose 1		Dose 2		Dose 3	
	Trumenba[b]	HAV/Saline[b]	Trumenba[b]	HAV/Saline[b]	Trumenba[b]	HAV/Saline[b]
Local Reaction	**N=2681**	**N=890**	**N=2545**	**N=843**	**N=2421**	**N=821**
Pain[c]						
Any[d]	86.7	47.0	77.7	15.2	76.0	34.0
Mild	41.1	36.5	39.4	12.3	34.1	23.8
Moderate	40.7	9.9	33.2	2.7	36.5	9.9
Severe	5.0	0.6	5.1	0.1	5.4	0.4
Redness[e]						
Any[d]	16.2	1.3	12.5	0.6	13.9	1.1
Mild	5.6	1.2	5.2	0.6	4.9	1.0
Moderate	8.8	0.1	6.1	0.0	6.8	0.1
Severe	1.9	0.0	1.1	0.0	2.2	0.0
Swelling[e]						
Any[d]	18.0	2.2	13.9	0.6	15.4	0.9
Mild	8.5	1.8	6.3	0.5	7.9	0.7
Moderate	8.8	0.4	7.3	0.1	6.8	0.1
Severe	0.7	0.0	0.2	0.0	0.7	0.0

[a] Study 1: National Clinical Trial (NCT) number NCT01830855.
[b] Trumenba was administered at 0, 2, and 6 months. HAV was administered at 0 and 6 months and saline was administered at 2 months.
[c] Mild (does not interfere with activity); moderate (interferes with activity); severe (prevents daily activity).
[d] "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.
[e] Mild (2.5-5.0 cm); moderate (>5.0-10.0 cm); severe (>10.0 cm).

Table 2: Percentages of Subjects 18 to 25 Years of Age (Study 2[a]) Reporting Local Adverse Reactions Within 7 Days After Each Vaccination

	Dose 1		Dose 2		Dose 3	
	Trumenba[b]	Saline[b]	Trumenba[b]	Saline[b]	Trumenba[b]	Saline[b]
Local Reaction	**N=2425**	**N=798**	**N=2076**	**N=706**	**N=1823**	**N=624**
Pain[c]						
Any[d]	84.2	11.8	79.3	7.8	80.4	6.7
Mild	42.3	10.7	42.2	6.8	36.1	6.4
Moderate	37.1	1.1	32.7	1.0	38.9	0.3
Severe	4.8	0.0	4.4	0.0	5.3	0.0
Redness[e]						
Any[d]	13.8	0.6	11.8	0.3	17.1	0.2
Mild	5.8	0.5	4.6	0.1	6.2	0.2
Moderate	7.1	0.0	6.3	0.0	8.6	0.0
Severe	0.9	0.1	0.9	0.1	2.3	0.0
Swelling[e]						
Any[d]	15.5	0.6	14.0	0.4	16.6	0.3
Mild	8.5	0.3	7.7	0.3	8.8	0.0
Moderate	6.8	0.3	6.0	0.1	7.2	0.3
Severe	0.2	0.1	0.3	0.0	0.5	0.0

[a] Study 2: National Clinical Trial (NCT) number NCT01352845.
[b] Trumenba was administered at 0, 2, and 6 months. Saline was administered at 0, 2, and 6 months.
[c] Mild (does not interfere with activity); moderate (interferes with activity); severe (prevents daily activity).
[d] "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.
[e] Mild (2.5-5.0 cm); moderate (>5.0-10.0 cm); severe (>10.0 cm).

In Study 1, mean duration of pain was 2.4 to 2.6 days (range 1-17 days), for redness 2.0 to 2.2 days (range 1-12 days) and for swelling 2.0 to 2.1 days (range 1-21 days) in the combined Trumenba group. In Study 2, mean duration of pain was 2.6 to 2.8 days (range 1-67 days), for redness 2.2 to 2.5 days (range 1-13 days) and for swelling 2.1 to 2.6 days (range 1-70 days) in the Trumenba group.

Tables 3 and 4 present the percentage and severity of reported solicited systemic adverse reactions within 7 days of each dose of Trumenba or control (HAV/saline or saline) for Study 1 and Study 2, respectively.

Table 3: Percentages of Subjects 10 to 18 Years of Age (Study 1[a]) Reporting Systemic Adverse Reactions and Use of Antipyretic Medications Within 7 Days After Each Vaccination

	Dose 1		Dose 2		Dose 3	
	Trumenba[b]	HAV/Saline[b]	Trumenba[b]	HAV/Saline[b]	Trumenba[b]	HAV/Saline[b]
Systemic Reaction	**N=2681**	**N=890**	**N=2545**	**N=843**	**N=2421**	**N=821**
Fever (≥38°C)[c]						
≥38.0°C	6.4	1.9	2.0	1.5	2.7	2.3
38.0°C to <38.5°C	4.0	1.3	1.2	0.7	1.8	1.3
38.5°C to <39.0°C	1.9	0.3	0.7	0.7	0.6	0.4
39.0°C to ≤40.0°C	0.5	0.2	0.1	0.1	0.3	0.5
>40.0°C	0.0	0.0	0.0	0.0	0.0	0.1
Vomiting[d]						
Any[e]	3.7	1.9	2.2	1.4	1.7	2.2
Mild	2.8	1.7	1.7	1.1	1.4	1.7
Moderate	0.9	0.2	0.4	0.4	0.3	0.5
Severe	0.0	0.0	0.0	0.0	0.0	0.0
Diarrhea[f]						
Any[e]	10.6	12.1	7.6	9.1	7.7	7.6
Mild	9.1	10.9	6.2	7.6	6.4	6.2
Moderate	1.3	1.1	1.3	1.2	1.0	1.1
Severe	0.3	0.1	0.1	0.4	0.3	0.2
Headache[g]						
Any[e]	51.8	37.2	37.8	28.1	35.4	24.8
Mild	28.7	24.0	20.2	15.7	18.9	13.5
Moderate	21.0	12.5	16.0	10.9	15.2	10.4
Severe	2.2	0.7	1.7	1.5	1.3	1.0

Table 3: Percentages of Subjects 10 to 18 Years of Age (Study 1[a]) Reporting Systemic Adverse Reactions and Use of Antipyretic Medications Within 7 Days After Each Vaccination (cont'd)

	Dose 1		Dose 2		Dose 3	
	Trumenba[b]	HAV/Saline[b]	Trumenba[b]	HAV/Saline[b]	Trumenba[b]	HAV/Saline[b]
Systemic Reaction	**N=2681**	**N=890**	**N=2545**	**N=843**	**N=2421**	**N=821**
Fatigue[g]						
Any[e]	54.0	40.3	38.3	26.3	35.9	24.4
Mild	27.8	23.5	20.6	13.2	18.4	13.5
Moderate	23.2	15.2	15.8	11.7	15.2	10.0
Severe	3.0	1.7	1.9	1.4	2.3	0.9
Chills[g]						
Any[e]	25.3	17.2	16.0	10.3	13.1	8.3
Mild	16.2	13.3	10.6	8.1	8.7	6.5
Moderate	8.0	3.5	4.8	1.8	3.8	1.7
Severe	1.2	0.4	0.6	0.5	0.5	0.1
Muscle pain (other than muscle pain at the injection site)[g]						
Any[e]	24.4	19.2	17.8	10.3	17.6	11.1
Mild	13.2	13.5	8.7	5.2	9.5	6.6
Moderate	10.1	5.4	7.9	4.5	7.2	4.3
Severe	1.2	0.3	1.2	0.6	0.8	0.2
Joint pain[g]						
Any[e]	21.9	13.6	16.7	9.1	16.0	8.9
Mild	11.8	8.3	8.4	5.0	8.9	5.5
Moderate	8.7	4.6	7.5	3.4	5.9	3.0
Severe	1.4	0.7	0.8	0.7	1.2	0.4
Use of antipyretic medication	20.7	10.4	13.6	8.9	12.7	6.8

[a] Study 1: National Clinical Trial (NCT) number NCT01830855.
[b] Trumenba was administered at 0, 2, and 6 months. HAV was administered at 0 and 6 months and saline was administered at 2 months.
[c] Study 1: Fever (≥38°C): N=2679, 2540, and 2414 for Trumenba at Dose 1, Dose 2, and Dose 3, respectively; N=890, 840, and 819 for HAV/saline at Dose 1, Dose 2, and Dose 3, respectively.
[d] Mild (1-2 times in 24 hours); moderate (>2 times in 24 hours); severe (requires intravenous hydration).
[e] "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.
[f] Mild (2-3 loose stools in 24 hours); moderate (4-5 loose stools in 24 hours); severe (6 or more loose stools in 24 hours).
[g] Mild (does not interfere with activity); moderate (interferes with activity); severe (prevents daily activity).

Table 4: Percentages of Subjects 18 to 25 Years of Age (Study 2[a]) Reporting Systemic Adverse Reactions and Use of Antipyretic Medications Within 7 Days After Each Vaccination

	Dose 1		Dose 2		Dose 3	
	Trumenba[b]	Saline[b]	Trumenba[b]	Saline[b]	Trumenba[b]	Saline[b]
Systemic Reaction	**N=2425**	**N=798**	**N=2076**	**N=706**	**N=1823**	**N=624**
Fever (≥38°C)[c]						
≥38.0°C	2.4	0.6	1.2	1.0	2.0	0.6
38.0°C to <38.5°C	1.6	0.4	0.7	0.6	1.4	0.5
38.5°C to <39.0°C	0.7	0.0	0.4	0.3	0.4	0.2
39.0°C to ≤40.0°C	0.0	0.3	0.1	0.1	0.1	0.0
>40.0°C	0.0	0.0	0.0	0.0	0.1	0.0
Vomiting[d]						
Any[e]	2.6	2.1	2.1	1.6	2.0	1.4
Mild	2.2	2.1	1.6	1.3	1.8	1.1
Moderate	0.4	0.0	0.5	0.3	0.2	0.3
Severe	0.0	0.0	0.0	0.0	0.0	0.0
Diarrhea[f]						
Any[e]	12.7	11.8	8.6	8.1	7.5	6.9
Mild	10.2	9.8	6.4	4.7	6.1	5.3
Moderate	2.4	1.9	1.7	2.8	1.2	1.3
Severe	0.2	0.1	0.5	0.6	0.2	0.3

Table 4: Percentages of Subjects 18 to 25 Years of Age (Study 2[a]) Reporting Systemic Adverse Reactions and Use of Antipyretic Medications Within 7 Days After Each Vaccination (cont'd)

	Dose 1		Dose 2		Dose 3	
	Trumenba[b]	Saline[b]	Trumenba[b]	Saline[b]	Trumenba[b]	Saline[b]
Systemic Reaction	**N=2425**	**N=798**	**N=2076**	**N=706**	**N=1823**	**N=624**
Headache[g]						
Any[e]	43.9	36.2	33.1	24.9	32.5	21.6
Mild	24.3	22.1	18.4	13.6	17.6	12.5
Moderate	17.9	13.5	13.3	10.1	13.3	8.3
Severe	1.6	0.6	1.4	1.3	1.6	0.8
Fatigue[g]						
Any[e]	50.9	39.8	39.2	27.3	39.3	24.5
Mild	25.4	23.2	20.6	13.9	18.9	13.1
Moderate	22.1	15.8	16.4	11.5	18.8	9.6
Severe	3.4	0.9	2.2	2.0	1.6	1.8
Chills[g]						
Any[e]	18.1	9.8	12.4	8.5	12.6	6.4
Mild	12.0	8.1	8.1	6.9	7.7	4.3
Moderate	4.9	1.6	3.5	1.6	4.2	2.1
Severe	1.1	0.0	0.8	0.0	0.8	0.0
Muscle pain (other than muscle pain at the injection site)[g]						
Any[e]	25.9	14.5	15.6	8.5	16.9	7.5
Mild	13.0	9.6	7.6	5.8	8.9	4.5
Moderate	11.3	4.4	7.1	2.3	6.8	2.9
Severe	1.6	0.5	0.8	0.4	1.2	0.2
Joint pain[g]						
Any[e]	19.6	10.9	15.1	6.5	12.6	5.3
Mild	10.3	6.9	8.1	3.7	6.6	2.9
Moderate	7.9	3.5	6.2	2.5	5.4	2.4
Severe	1.4	0.5	0.9	0.3	0.6	0.0
Use of antipyretic medication	13.4	8.9	12.3	7.6	12.8	6.6

[a] Study 2: National Clinical Trial (NCT) number NCT01352845.
[b] Trumenba was administered at 0, 2, and 6 months. Saline was administered at 0, 2, and 6 months.
[c] Study 2: Fever (≥38°C): N=2415, 2067, and 1814 for Trumenba at Dose 1, Dose 2, and Dose 3, respectively; N=796, 705, and 621 for saline at Dose 1, Dose 2, and Dose 3, respectively.
[d] Mild (1-2 times in 24 hours); moderate (>2 times in 24 hours); severe (requires intravenous hydration).
[e] "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.
[f] Mild (2-3 loose stools in 24 hours); moderate (4-5 loose stools in 24 hours); severe (6 or more loose stools in 24 hours).
[g] Mild (does not interfere with activity); moderate (interferes with activity); severe (prevents daily activity).

The frequencies of adverse reactions were highest after the first dose regardless of the schedule. After subsequent doses, the frequencies of adverse reactions were similar regardless of dose number and schedule.

Serious Adverse Events

Overall in clinical studies in which 15,227 subjects 10 through 25 years of age received at least one dose of Trumenba, serious adverse events (SAEs) were reported by 269 (1.8%) subjects.

Among the 8 controlled studies (Trumenba N=13,275, control N=5,501), SAEs were reported by 213 (1.6%) subjects and by 106 (1.9%) subjects who received at least one dose of Trumenba or control, respectively.

Non-serious Adverse Events

Overall in clinical studies in which 15,227 subjects 10 through 25 years of age received Trumenba, non-serious AEs within 30 days after any dose were reported in 4,463 (29.3%) subjects. Among the 8 controlled studies (Trumenba N=13,275, control N=5,501), AEs that occurred within 30 days of vaccination were reported in 4,056 (30.6%) subjects who received Trumenba and 1,539 (28.0%) subjects in the control group, for individuals who received at least one dose. AEs that occurred at a frequency of at least 2% and were more frequently observed in subjects who received Trumenba than subjects in the control group were injection site pain, fever, and headache.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of Trumenba. Because these reactions are reported voluntarily froma population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to product exposure.

Immune System Disorders: Hypersensitivity reactions, including anaphylactic reactions.

Nervous system disorder: Syncope (fainting).

7 DRUG INTERACTIONS

In clinical trials, Trumenba was administered concomitantly with HPV4 in adolescents 11 to <18 years of age and with MCV4 and Tdap in adolescents 10 to <13 years of age *[see Clinical Studies (14.0) and Adverse Reactions (6.0)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. There are no adequate and well-controlled studies of Trumenba in pregnant women. Available human data on Trumenba administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

Two developmental toxicity studies were performed in female rabbits administered Trumenba prior to mating and during gestation. The dose was 0.5 mL at each occasion (a single human dose is 0.5 mL). These studies revealed no evidence of harm to the fetus or offspring (until weaning) due to Trumenba [see Animal Data].

Animal Data

Two developmental toxicity studies were performed in female rabbits. Animals were administered Trumenba by intramuscular injection 17 days and 4 days prior to mating and on gestation Days 10 and 24. The dose was 0.5 mL at each occasion (a single human dose is 0.5 mL). No adverse effects on pre-weaning development up to post-natal day 21 were observed. There were no fetal malformations or variations observed due to the vaccine.

8.2 Lactation

Risk Summary

Available data are not sufficient to assess the effects of Trumenba 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 Trumenba and any potential adverse effects on the breastfed child from Trumenba 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 have not been established in children <10 years of age. In a clinical study, 90% of infants <12 months of age who were vaccinated with a reduced dosage formulation had fever.

8.5 Geriatric Use

Safety and effectiveness of Trumenba in adults older than 65 years of age have not been established.

11 DESCRIPTION

Trumenba is a sterile suspension composed of two recombinant lipidated factor H binding protein (fHBP) variants from *N. meningitidis* serogroup B, one from fHBP subfamily A and one from subfamily B (A05 and B01, respectively).[1] The proteins are individually produced in *E. coli*. Production strains are grown in defined fermentation growth media to a specific density. The recombinant proteins are extracted from the production strains and purified through a series of column chromatography steps. Polysorbate 80 (PS80) is added to the drug substances and is present in the final drug product.

Each 0.5 mL dose contains 60 micrograms of each fHBP variant (total of 120 micrograms of protein), 0.018 mg of PS80 and 0.25 mg of Al^{3+} as $AlPO_4$ in 10 mM histidine buffered saline at pH 6.0.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Protection against invasive meningococcal disease is conferred mainly by complement-mediated antibody-dependent killing of *N. meningitidis*. The effectiveness of Trumenba was assessed by measuring serum bactericidal activity using human complement (hSBA).

fHBP is one of many proteins found on the surface of meningococci and contributes to the ability of the bacterium to avoid host defenses. fHBPs can be categorized into two immunologically distinct subfamilies, A and B.[1] The susceptibility of serogroup B meningococci to complement-mediated antibody-dependent killing following vaccination with Trumenba is dependent on both the antigenic similarity of the bacterial and vaccine fHBPs, as well as the amount of fHBP expressed on the surface of the invading meningococci.

13 NONCLINICAL TOXICOLOGY

Trumenba has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility in males. Vaccination of female rabbits with Trumenba had no effect on fertility *[see Pregnancy (8.1)]*.

14 CLINICAL STUDIES

The immunogenicity of Trumenba following the three-dose schedule (0, 2, and 6 months) was evaluated in individuals 10 to 25 years of age in the U.S., Canada, and Europe (Studies 1 and 2) and following the two-dose (0 and 6 months) and three-dose schedules (0, 1-2, and 6 months) in individuals 11 to 18 years of age in Europe (Study 3). Serum bactericidal antibodies were measured with hSBA assays that used each of four meningococcal serogroup B strains. These four primary test strains express fHBP variants representing the two subfamilies (A and B) and, when taken together, are representative of meningococcal serogroup B strains causing invasive disease in the U.S. and Europe. The studies assessed the proportions of subjects with a 4-fold or greater increase in hSBA titer for each of the four primary strains. The studies also assessed the composite response to the four primary strains combined (proportion of subjects who achieved a hSBA titer greater than or equal to 1:8 (three strains) or 1:16 (one strain). To assess the effectiveness of the three-dose schedule of Trumenba against diverse meningococcal serogroup B strains, the proportion of subjects achieving a defined hSBA titer post-dose 3 was evaluated against a panel of 10 additional strains, each expressing a different fHBP variant.

14.1 Immunogenicity

The hSBA responses to each of the primary strains observed in U.S. subjects after the third dose of Trumenba are presented for Study 1 and Study 2 in Table 5.

Table 5: Percentages of U.S. Individuals 10 to 25 Years of Age With ≥4-fold rise in hSBA Titer and Composite Response Following Administration of Trumenba on a 0-, 2-, and 6-Month Schedule for Four Primary Strains (Studies 1 and 2)[a,b,c,d]

		Study 1 (10 to 18 Years of Age)		Study 2 (18 to 25 Years of Age)	
		n	% (95% CI)[e]	n	% (95% CI)[e]
Subfamily/Subgroup fHBP Variant[f,g]					
≥4-Fold Increase					
PMB80 (A22)	Dose 3	587	86.2 (83.1, 88.9)	644	81.1 (77.8, 84.0)
PMB2001 (A56)	Dose 3	526	92.0 (89.4, 94.2)	621	90.7 (88.1, 92.8)
PMB2948 (B24)	Dose 3	585	81.9 (78.5, 84.9)	634	83.9 (80.8, 86.7)
PMB2707 (B44)	Dose 3	555	88.3 (85.3, 90.8)	643	79.3 (76.0, 82.4)
Composite hSBA response[h]					
	Before Dose 1	507	0.6 (0.1, 1.7)	610	3.3 (2.0, 5.0)
	Dose 3	537	85.7 (82.4, 88.5)	625	82.4 (79.2, 85.3)

Abbreviations: CI=confidence interval; fHBP=factor H binding protein; hSBA=serum bactericidal assay using human complement; LLOQ=lower limit of quantitation; LOD=limit of detection.
Note: LLOQ = 1:16 for A22; 1:8 for A56, B24, and B44.
Note: The 4-fold increase is defined as follows: (1) For subjects with a baseline hSBA titer <1:4, a response is defined as an hSBA titer ≥1:16. (2) For subjects with a baseline hSBA titer ≥1:4, a response is defined as an hSBA titer ≥4 times the LLOQ or ≥4 times the baseline titer, whichever was higher.
Note: Pre-specified criteria for assessment of hSBA responses (4-fold rise in titer to each primary test strain, and titer above LLOQ for all four primary test strains) among U.S. subjects were met in these studies.
[a] Evaluable immunogenicity population.
[b] Study 1 = NCT01830855 and Study 2 = NCT01352845.
[c] Study 1: Group 1 (0, 2, and 6 months).
[d] Study 2: Group 1 (0, 2, and 6 months).
[e] Exact 2-sided confidence interval (Clopper-Pearson method) based upon the observed proportion of subjects.
[f] The strains expressing variants A22, A56, B24, and B44 correspond to strains PMB80, PMB2001, PMB2948, and PMB2707, respectively.
[g] For the third dose, serum was obtained approximately 1 month after vaccination.
[h] Composite response = hSBA ≥ LLOQ for all 4 primary meningococcal B strains.

The hSBA responses against a panel of 10 additional strains observed in U.S. subjects after the third dose of Trumenba are presented for Study 1 and Study 2 in Table 6.

Table 6. Percentages of U.S. Individuals 10 to 25 Years of Age With a hSBA Titer ≥ LLOQ Against 10 Additional Strains Following Administration of Trumenba on a 0-, 2-, and 6-Month Schedule (Study 1 and Study 2)-[a,b]

		Study 1 (10 to 18 Years of Age)		Study 2 (18 to 25 Years of Age)	
		n	% (95% CI)[c]	n	% (95% CI)[c]
Subfamily/Subgroup fHBP Variant[d,e]					
A/N1C1 PMB3175 (A29)	Before Dose 1	169	11.2 (6.9, 17.0)	160	23.8 (17.4, 31.1)
	Dose 3	176	98.9 (96.0, 99.9)	162	98.8 (95.6, 99.9)
A/N1C2 PMB3010 (A06)	Before Dose 1	178	7.9 (4.4, 12.8)	166	10.8 (6.6, 16.6)
	Dose 3	179	97.8 (94.4, 99.4)	164	89.0 (83.2, 93.4)
A/N2C1 PMB3040 (A07)	Before Dose 1	170	37.6 (30.3, 45.4)	165	55.8 (47.8, 63.5)
	Dose 3	178	96.1 (92.1, 98.4)	165	95.2 (90.7, 97.9)
PMB824 (A12)	Before Dose 1	180	5.0 (2.3, 9.3)	166	4.8 (2.1, 9.3)
	Dose 3	180	76.1 (69.2, 82.1)	165	66.7 (58.9, 73.8)
PMB1672 (A15)	Before Dose 1	170	15.9 (10.7, 22.3)	159	30.2 (23.2, 38.0)
	Dose 3	166	86.7 (80.6, 91.5)	159	89.9 (84.2, 94.1)
A/N2C2 PMB1989 (A19)	Before Dose 1	174	5.7 (2.8, 10.3)	158	23.4 (17.1, 30.8)
	Dose 3	173	91.9 (86.8, 95.5)	163	94.5 (89.8, 97.4)
B/N6 PMB1256 (B03)	Before Dose 1	183	2.2 (0.6, 5.5)	164	5.5 (2.5, 10.2)
	Dose 3	181	92.3 (87.4, 95.7)	161	84.5 (77.9, 89.7)
PMB866 (B09)	Before Dose 1	180	12.2 (7.8, 17.9)	165	13.9 (9.0, 20.2)
	Dose 3	182	85.7 (79.8, 90.5)	162	72.2 (64.7, 79.0)
PMB431 (B15)	Before Dose 1	180	27.8 (21.4, 34.9)	163	33.1 (26.0, 40.9)
	Dose 3	183	97.3 (93.7, 99.1)	163	95.7 (91.4, 98.3)
PMB648 (B16)	Before Dose 1	180	6.7 (3.5, 11.4)	161	11.8 (7.3, 17.8)
	Dose 3	180	83.9 (77.7, 88.9)	159	72.3 (64.7, 79.1)

Abbreviations: CI=confidence interval; fHBP=factor H binding protein; hSBA=serum bactericidal assay using human complement; LLOQ=lower limit of quantitation.
Note: LLOQ = 1:16 for A06, A12, and A19; 1:8 for A07, A15, A29, B03, B09, B15, and B16.
[a] The evaluable immunogenicity population was used for the analysis.
[b] Study 1 = NCT01830855 and Study 2 = NCT01352845.
[c] Exact 2-sided confidence interval (Clopper and Pearson) based upon the observed proportion of subjects.
[d] The strains expressing variants A06, A12, A19, A07, A15, A29, B03, B09, B15, and B16 correspond to strains PMB3010, PMB824, PMB1989, PMB3040, PMB1672, PMB3175, PMB1256, PMB866, PMB431, and PMB648, respectively.
[e] For the third dose, serum was obtained approximately 1 month after vaccination.

In Study 3, Trumenba was administered according to different schedules, including Group 1 (0, 1, and 6 months), Group 2 (0, 2, and 6 months) and Group 3 (0 and 6 months). The hSBA responses observed after the second dose in Groups 1, 2, and 3 and completion of the three-dose series in Group 1 and 2 are presented in Table 7.

Table 7: Percentages of European Individuals 11 to 18 Years of Age With a ≥4-Fold Increase in hSBA Titer and Composite Response[a,b]

	Group 1 3-Dose Schedule (0, 1, and 6 Months)[c]	Group 2 3-Dose Schedule (0, 2, and 6 Months)[d]	Group 3 2-Dose Schedule (0 and 6 Months)[e]
fHBP Variant[f,g]	% (95% CI)[h]	% (95% CI)[h]	% (95% CI)[h]
≥4-Fold Increase			
PMB80 (A22)			
Dose 2	58.8 (51.4, 66.0)	72.5 (66.4, 78.0)	82.3 (76.3, 87.3)
Dose 3	77.6 (70.9, 83.4)	87.7 (81.6, 92.3)	NA
PMB2001 (A56)			
Dose 2	87.8 (82.2, 92.2)	90.7 (86.2, 94.1)	90.1 (85.1, 93.8)
Dose 3	91.2 (86.1, 94.9)	93.8 (88.8, 97.0)	NA
PMB2948 (B24)			
Dose 2	51.1 (43.6, 58.5)	54.2 (47.7, 60.7)	64.5 (57.4, 71.1)
Dose 3	74.1 (67.1, 80.2)	78.3 (71.1, 84.4)	NA
PMB2707 (B44)			
Dose 2	48.1 (40.7, 55.6)	53.4 (46.8, 59.9)	66.0 (58.9, 72.6)
Dose 3	80.9 (74.5, 86.2)	78.6 (71.4, 84.7)	NA
Composite Response[g,i]			
Before Dose 1	4.6 (2.0, 8.8)	2.2 (0.7, 5.0)	1.5 (0.3, 4.4)
Dose 2	52.0 (44.3, 59.7)	52.0 (45.3, 58.6)	72.9 (65.9, 79.1)
Dose 3	80.3 (73.7, 85.9)	81.8 (74.9, 87.4)	NA

Abbreviations: CI=confidence interval; fHBP=factor H binding protein; hSBA=serum bactericidal assay using human complement; LLOQ=lower limit of quantitation; NA=not applicable.
Note: LLOQ = 1:16 for PMB80 (A22) and 1:8 for PMB2001 (A56), PMB2948 (B24), and PMB2707 (B44).
Note: The ≥4-fold increase is defined as follows: (1) For subjects with a baseline hSBA titer <1:4, a ≥4-fold increase was defined as an hSBA titer ≥1:16. (2) For subjects with a baseline hSBA titer ≥1:4, a ≥4-fold increase was defined as an hSBA titer ≥4 times the LLOQ or ≥4 times the baseline titer, whichever was higher.
[a] Per-schedule Evaluable populations. Dose 2 data include subjects who received two doses, irrespective of whether they received the third dose.
[b] Study 3: NCT01299480.
[c] Group 1 (0, 1, and 6 months). The denominators ranged from 173 to 187 after Dose 2 and 178 to 188 after Dose 3, depending on the strain.
[d] Group 2 (0, 2, and 6 months). The denominators ranged from 229 to 240 after Dose 2 and 159 to 162 after Dose 3, depending on the strain.
[e] Group 3 (0 and 6 months). The denominators ranged from 188 to 203 after Dose 2, depending on the strain.
[f] The strains expressing variant A22, A56, B24, and B44 correspond to strains PMB80, PMB2001, PMB2948, and PMB2707, respectively.
[g] For the second and third doses, serum was obtained approximately 1 month after vaccination.
[h] Exact 2-sided confidence interval (Clopper and Pearson) based upon the observed proportion of subjects.
[i] Composite response = hSBA ≥LLOQ for all 4 primary meningococcal B strains.

14.2 Concomitant Vaccine Administration

Study 4 evaluated the immunogenicity of concomitantly administered Trumenba and Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant (HPV4) (Merck & Co, Inc.). U.S. subjects 11 to <18 years of age were randomized into three groups: Group 1 received Trumenba and HPV4 (N=992), Group 2 received Trumenba and saline (N=990), and Group 3 received saline and HPV4 (N=501). All vaccines were administered according to a 0, 2 and 6 month schedule. Immune responses were evaluated by comparisons of geometric mean titer [GMT] for each HPV type at 1 month after the third HPV4 vaccination (Group 1 vs. Group 3), and hSBA GMTs using two meningococcal serogroup B strains [variants A22 and B24] 1 month after the third Trumenba vaccination (Group 1 vs. Group 2). The noninferiority criteria for the comparisons of GMTs [lower limit of the 2-sided 95% confidence interval (CI) of the GMT ratio (Group 1/Group 3 for HPV and Group 1/Group 2 for meningococcal serogroup B strains) >0.67] were met for three HPV types (6, 11 and 16) and for the meningococcal serogroup B strains tested. For HPV-18, the lower bound of the 95% CI for the GMT ratio was 0.62 at one month after the third HPV4 vaccination.

Study 5 evaluated the immunogenicity of concomitantly administered Trumenba and Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine (MCV4) (Sanofi Pasteur Inc.) and Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) (Sanofi Pasteur Ltd.) vaccines. U.S. subjects 10 to <13 years of age were randomized into three groups: Group 1 received Trumenba at 0, 2, and 6 months, and MCV4 and Tdap were coadministered with the first Trumenba dose (N=883). Group 2 received saline at 0, 2 and 6 months, and MCV4 and Tdap were coadministered with the first saline injection (N=870). Group 3 received Trumenba at 0, 2 and 6 months, and saline was coadministered with the first Trumenba dose (N=875). Immune responses were evaluated by comparisons of GMTs for each of the MCV4 and Tdap antigens 1 month after the first Trumenba vaccination, and hSBA GMTs using two meningococcal serogroup B strains [variants A22 and B24] 1 month after the third Trumenba vaccination. The noninferiority criteria for the comparisons of GMTs [lower limit of the 2-sided 95% CI of the GMT ratio (Group 1/Group 3 for meningococcal serogroup B strains and Group 1/Group 2 for MCV4 and Tdap) >0.67] were met for all antigens.

15 REFERENCES

1. Wang X, et al. Prevalence and genetic diversity of candidate vaccine antigens among invasive *Neisseria meningitidis* isolates in the U.S. Vaccine 2011; 29:4739-4744.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

Trumenba is supplied in the following strengths and package configurations:

Prefilled Syringe, 1 Dose (10 per package) – NDC 0005-0100-10.

Prefilled Syringe, 1 Dose (5 per package) – NDC 0005-0100-05.

Prefilled Syringe, 1 Dose (1 per package) – NDC 0005-0100-02 (This Package Not for Sale).

After shipping, Trumenba may arrive at temperatures between 2°C to 25°C (36°F to 77°F).

The tip cap and rubber plunger of the prefilled syringe are not made with natural rubber latex.

16.2 Storage and Handling

Upon receipt, store refrigerated at 2°C to 8°C (36°F to 46°F).

Store syringes in the refrigerator horizontally (laying flat on the shelf) to minimize the re-dispersion time.

Do not freeze. Discard if the vaccine has been frozen.

17 PATIENT COUNSELING INFORMATION

Prior to administration of this vaccine, the healthcare professional should inform the individual, parent, guardian, or other responsible adult of the following:

- The importance of completing the immunization series.
- Report any suspected adverse reactions to a healthcare professional.

Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Manufactured by

Pfizer

Wyeth Pharmaceuticals Inc

A subsidiary of Pfizer Inc, Philadelphia, PA 19101

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LAB-0722-8.0

CPT Code 90621