TRUMENBA- meningococcal group b vaccine injection, suspension
Wyeth Pharmaceutical Division of Wyeth Holdings LLC

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

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)

DOSAGE AND ADMINISTRATION

- For intramuscular use only. (2)
- **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)
- **Three-dose schedule:** Administer a dose (0.5 mL) at 0, 1–2, and 6 months. (2.1)

DOSAGE FORMS AND STRENGTHS

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

CONTRAINDICATIONS

Severe allergic reaction (e.g., anaphylaxis) to any component 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: 1/2026

FULL PRESCRIBING INFORMATION: CONTENTS*

* 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.

2 DOSAGE AND ADMINISTRATION

For intramuscular use only.

2.1 Dose and Schedule

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.

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

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

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 (e.g. anaphylaxis) to any component of Trumenba *[see Description (11)]*.

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)]*.

5.3 Limitation of Vaccine Effectiveness

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%).

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 16,284 subjects 10 through 25 years of age in 12 clinical studies (9 randomized controlled and 3 supportive non-controlled studies) conducted in the U.S., Europe, Canada, Chile, and Australia. A total of 11,991 subjects 10 through 18 years of age, and 4,293 subjects 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 (Serogroups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (MenACWY) (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 (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 1 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. Among participants in clinical trials B1971009 (Study 1009), B1971016 (Study 1016), and B1971057 (Study 1057), 41.3% to 51.5% were male, 76.1% to 87.3% were White, 8.1% to 20.8% were Black or African-American, <2% were Asian, and 5.8% to 17.1% were Hispanic/Latino.

Solicited Local and Systemic Adverse Reactions

Study 1057 was a randomized, observer-blinded, multicenter trial in the U.S. and Europe. In this study, 1057 subjects 10 through 25 years of age received at least 1 dose of Trumenba on a 0- and 6-month schedule. Trumenba was co-administered with Meningococcal (Groups A, C, Y, W-135) Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine (MenACWY) (GSK Vaccines, SRL) for the first dose.

Study 1009 was a randomized, active-controlled, observer-blinded, multicenter trial in the U.S., Canada, and Europe in which 2,693 subjects 10 through 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.

Study 1016 was a randomized, placebo-controlled, observer-blinded, multicenter trial in the U.S., Canada, and Europe in which 2,471 subjects 18 through 25 years of age received at least 1 dose of Trumenba and 822 subjects received saline on a 0-, 2,- and 6- month schedule.

Local adverse reactions at the injection site were assessed in the three studies.

Tables 1, 2, and 3 present the percentage and severity of reported local adverse reactions within 7 days following each dose of Trumenba for Study 1057 and following each dose of Trumenba or control (HAV/saline or saline) for Study 1009 and Study 1016, respectively.

In Studies 1009 and 1016, local adverse reactions were reported more frequently following Trumenba compared to control (see Tables 2 and 3, respectively).

Table 1: Percentages of Subjects 10 through 25 Years of Age (Study 1057*) Reporting Local Adverse Reactions Within 7 Days After Each Vaccination

	Dose 1	**Dose 2**
	Trumenba+MenACWY-CRM†	**Trumenba†**
Local Reaction	**N=1044**	**N=903**
Pain‡		
Any§	85.0	82.2
Mild	41.2	38.9
Moderate	39.1	37.9
Severe	4.7	5.4
Redness¶		
Any§ (≥ 2.5 cm)	16.9	14.7
Mild	6.8	5.2
Moderate	8.0	8.4
Severe	2.0	1.1
Swelling¶		
Any§ (≥ 2.5 cm)	17.0	14.3
Mild	9.8	6.4
Moderate	6.9	7.5
Severe	0.3	0.3

* Study 1057: National Clinical Trial (NCT) number NCT03135834.
† Trumenba and MenACWY-CRM were administered at 0 month followed by Trumenba alone at 6 months. Local reactions were recorded at the Trumenba injection site only.
‡ Mild (does not interfere with activity); moderate (interferes with activity); severe (prevents daily activity).
§ "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.
¶ Mild (2.5–5.0 cm); moderate (>5.0–10.0 cm); severe (>10.0 cm).

Table 2: Percentages of Subjects 10 through 18 Years of Age (Study 1009*) Reporting Local Adverse Reactions Within 7 Days After Each Vaccination

	Dose 1		Dose 2		Dose 3	
	Trumenba†	HAV/Saline†	Trumenba†	HAV/Saline†	Trumenba†	HAV/Saline†
Local Reaction	**N=2681**	**N=890**	**N=2545**	**N=843**	**N=2421**	**N=821**
Pain‡						
Any§	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¶						
Any§ (≥ 2.5 cm)	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¶						
Any§ (≥ 2.5 cm)	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

* Study 1009: NCT01830855.
† Trumenba was administered at 0, 2, and 6 months. HAV was administered at 0 and 6 months and saline was administered at 2 months.
‡ Mild (does not interfere with activity); moderate (interferes with activity); severe (prevents daily activity).
§ "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.
¶ Mild (2.5–5.0 cm); moderate (>5.0–10.0 cm); severe (>10.0 cm).

Table 3: Percentages of Subjects 18 through 25 Years of Age (Study 1016*) Reporting Local Adverse Reactions Within 7 Days After Each Vaccination

	Dose 1		Dose 2		Dose 3	
	Trumenba†	Saline†	Trumenba†	Saline†	Trumenba†	Saline†
Local Reaction	**N=2425**	**N=798**	**N=2076**	**N=706**	**N=1823**	**N=624**
Pain‡						
Any§	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¶						
Any§ (≥ 2.5 cm)	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¶						
Any§ (≥ 2.5 cm)	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

* Study 1016: NCT01352845.
† Trumenba was administered at 0, 2, and 6 months. Saline was administered at 0, 2, and 6 months.
‡ Mild (does not interfere with activity); moderate (interferes with activity); severe (prevents daily activity).
§ "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.
¶ Mild (2.5–5.0 cm); moderate (>5.0–10.0 cm); severe (>10.0 cm).

In Study 1057, among Trumenba recipients, mean duration of pain was 2.7 days (range 1–17 days) after the first vaccination and 2.7 days (range 1–12 days) after the second vaccination; redness was 2.2 days (range 1–9 days) and 2.4 days (1–11 days), respectively; and swelling was 2.2 days (range 1–17 days) and 2.5 days (range 1–27 days), respectively.

In Study 1009, mean duration of pain was 2.4 to 2.6 days (range 1–17 days), redness was 2.0 to 2.2 days (range 1–12 days) and swelling was 2.0 to 2.1 days (range 1–21 days) for the three-dose series in the Trumenba groups. In Study 1016, mean duration of pain was 2.6 to 2.8 days (range 1–67 days), redness was 2.2 to 2.5 days (range 1–13 days) and swelling was 2.1 to 2.6 days (range 1–70 days) in the Trumenba group.

Tables 4, 5, and 6 present the percentage and severity of reported solicited systemic adverse reactions within 7 days of each dose of Trumenba for Study 1057 and within 7 days of each dose of Trumenba or control (HAV/saline or saline) for Study 1009 and Study 1016, respectively.

Table 4: Percentages of Subjects 10 through 25 Years of Age (Study 1057*) Reporting Systemic Adverse Reactions and Use of Antipyretic Medications Within 7 Days After Each Vaccination

Systemic Reaction	Dose 1	Dose 2
	Trumenba+MenACWY-CRM†	Trumenba†
	N=1044	N=903
Fever (≥38°C)		
≥38.0°C	6.7	3.2
38.0°C to	4.0	1.9

<38.5°C		
38.5°C to <39.0°C	2.1	0.7
39.0°C to ≤40.0°C	0.6	0.7
>40.0°C	0.0	0.0
Vomiting ‡		
Any§	3.7	2.8
Mild	2.9	2.0
Moderate	0.9	0.8
Severe	0.0	0.0
Diarrhea¶		
Any§	14.1	10.6
Mild	10.7	7.6
Moderate	3.3	2.5
Severe	0.1	0.4
Headache#		
Any§	46.5	41.6
Mild	25.1	23.1
Moderate	19.0	16.5
Severe	2.4	2.0
Fatigue#		
Any§	51.9	45.2
Mild	25.4	23.0
Moderate	23.7	19.2
Severe	2.9	3.0
Chills#		
Any§	18.5	18.5
Mild	11.5	11.6
Moderate	5.7	6.2
Severe	1.2	0.7
Muscle pain (other than muscle pain at the injection site)#		
Any§	28.4	21.4
Mild	15.8	11.5
Moderate	11.6	7.8
Severe	1.1	2.1
Joint pain#		
Any§	19.6	18.7
Mild	10.2	11.2
Moderate	8.6	6.5
Severe	0.8	1.0
Use of antipyretic medication	18.6	14.4

* Study 1057: NCT03135834.
† Trumenba and MenACWY-CRM were administered at 0 month followed by Trumenba alone at 6 months.
‡ Mild (1–2 times in 24 hours); moderate (>2 times in 24 hours); severe (requires

intravenous hydration).
§ "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.
¶ 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).
# Mild (does not interfere with activity); moderate (some interference with activity); severe (prevents daily routine activity).

Table 5: Percentages of Subjects 10 through 18 Years of Age (Study 1009*) Reporting Systemic Adverse Reactions and Use of Antipyretic Medications Within 7 Days After Each Vaccination

	Dose 1		Dose 2		Dose 3	
	Trumenba†	HAV/Saline†	Trumenba†	HAV/Saline†	Trumenba†	HAV/Saline†
Systemic Reaction	**N=2681**	**N=890**	**N=2545**	**N=843**	**N=2421**	**N=821**
Fever (≥38°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§						
Any¶	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#						
Any¶	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♭						
Any¶	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
Fatigue♭						
Any¶	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[Þ]						
Any[¶]	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)[Þ]						
Any[¶]	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[Þ]						
Any[¶]	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

* Study 1009: NCT01830855.
† Trumenba was administered at 0, 2, and 6 months. HAV was administered at 0 and 6 months and saline was administered at 2 months.
‡ Study 1009: 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.
§ Mild (1–2 times in 24 hours); moderate (>2 times in 24 hours); severe (requires intravenous hydration).
¶ "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.
# 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).
Þ Mild (does not interfere with activity); moderate (interferes with activity); severe (prevents daily activity).

Table 6: Percentages of Subjects 18 through 25 Years of Age (Study 1016[*]) Reporting Systemic Adverse Reactions and Use of Antipyretic Medications Within 7 Days After Each Vaccination

	Dose 1		**Dose 2**		**Dose 3**	
	Trumenba[†]	**Saline[†]**	**Trumenba[†]**	**Saline[†]**	**Trumenba[†]**	**Saline[†]**
Systemic Reaction	**N=2425**	**N=798**	**N=2076**	**N=706**	**N=1823**	**N=624**
Fever (≥38°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[§]						
Any[¶]	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[#]						
Any[¶]	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
Headache[Þ]						
Any[¶]	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[Þ]						
Any[¶]	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[Þ]						
Any[¶]	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)[Þ]						
Any[¶]	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[Þ]						
Any[¶]	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

* Study 1016: NCT01352845.
† Trumenba was administered at 0, 2, and 6 months. Saline was administered at 0, 2, and 6 months.
‡ Study 1016: 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.
§ Mild (1–2 times in 24 hours); moderate (>2 times in 24 hours); severe (requires intravenous hydration).
¶ "Any" is defined as the cumulative frequency of subjects who reported a reaction as "mild", "moderate", or "severe" within 7 days of vaccination.

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).
Þ Mild (does not interfere with activity); moderate (interferes with activity); severe (prevents daily activity).

In three early phase studies in which it was solicited, nausea was reported in up to 24% of adolescents.

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

Among the 8 controlled studies investigating the three-dose (0, 1–2, and 6 months) schedule (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

Among the 8 controlled studies investigating the three-dose (0, 1–2, and 6 months) schedule (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 at least one dose of Trumenba and 1,539 (28.0%) subjects in the control group 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 from a 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 through 17 years of age and with MenACWY and Tdap in adolescents 10 through 12 years of age *[see Clinical Studies (14) and Adverse Reactions (6)]*.

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. Clinical data strongly suggest that a two-dose regimen of Trumenba would be ineffective in children 1 to <10 years of age.

8.5 Geriatric Use

Safety and effectiveness of Trumenba in adults >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 described in this section is based on results from four clinical studies:

- Following the two-dose schedule (0 and 6 months) in subjects 10 through 25 years of age in the U.S. and Europe (Study 1057);
- Following the three-dose schedule (0, 2, and 6 months) in subjects 10 through 25 years of age in the U.S., Canada, and Europe (Studies 1009 and 1016); and
- Following the two-dose (0 and 6 months) and three-dose schedules (0, 1–2, and 6 months) in subjects 11 through 18 years of age in Europe (Study 1012).

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) 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] and 1:16 [one strain]). To assess the effectiveness of the two- and three-dose schedules of Trumenba against diverse meningococcal serogroup B strains, the proportion of subjects achieving a defined hSBA titer (≥LLOQ) following completion of the two- or three-dose series 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 after the second dose of Trumenba in Study 1057 are presented in Table 7.

Table 7: Percentages of Subjects 10 through 25 Years of Age With ≥4-fold Rise in hSBA Titer and Composite Response Following Administration of Trumenba on a 0-and 6-Month Schedule for Four Primary Strains (Study 1057)*,†

fHbp Variant‡		N§	% (95% CI)¶
≥4-Fold Increase			
PMB80 (A22)	Dose 2	827	73.8 (70.6, 76.7)
PMB2001 (A56)	Dose 2	823	95.0 (93.3, 96.4)
PMB2948 (B24)	Dose 2	835	67.4 (64.1, 70.6)
PMB2707 (B44)	Dose 2	850	86.4 (83.9, 88.6)
Composite hSBA Response#			
	Before Dose 1	799	1.8 (1.0, 2.9)
	Dose 2	814	74.3 (71.2, 77.3)

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 ≥ LOD and < LLOQ, a response is defined as an hSBA titer ≥4 times the LLOQ. (3) For subjects with a baseline hSBA titer ≥ LLOQ, a response is defined as an hSBA titer ≥4 times the baseline titer.
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 subjects in the U.S. and Europe were met in this study for all test strains except strain A22. Pre-specified criteria for the lower bound of the 95% CI for 4-fold rise in titer were set at 75%, 85%, 55%, and 60%, respectively, for A22, A56, B24, and B44, and 65% for the composite hSBA response for all four primary test strains.

* Evaluable immunogenicity population.
† Study 1057: NCT03135834.
‡ For the second dose, serum was obtained approximately 1 month after vaccination.
§ For ≥4-fold increase, N=number of subjects with valid and determinate hSBA titers for the given strain at both the specified time point and baseline. For composite

hSBA response, N=number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. U.S. subjects constituted approximately 80% of the total subjects evaluated for immunogenicity.

¶ Exact 2-sided confidence interval (Clopper-Pearson method) based upon the observed proportion of subjects.

Composite response = hSBA ≥ LLOQ for all 4 primary meningococcal B strains.

The hSBA responses after the second dose of Trumenba in Study 1057 against a panel of 10 additional strains representing the diversity of meningococcal fHbp types prevalent among strains circulating in the US are presented in Table 8.

Table 8. Percentages of Subjects 10 through 25 Years of Age With a hSBA Titer ≥ LLOQ Against 10 Additional Strains Following Administration of Trumenba on a 0- and 6-Month Schedule (Study 1057)*,†

fHbp Variant‡		N§	% (95% CI)¶
PMB3175 (A29)	Before Dose 1	166	4.8 (2.1, 9.3)
	Dose 2	166	95.2 (90.7, 97.9)
PMB3010 (A06)	Before Dose 1	157	5.7 (2.7, 10.6)
	Dose 2	159	89.3 (83.4, 93.6)
PMB3040 (A07)	Before Dose 1	150	32.0 (24.6, 40.1)
	Dose 2	157	96.8 (92.7, 99.0)
PMB824 (A12)	Before Dose 1	154	5.2 (2.3, 10.0)
	Dose 2	157	83.4 (76.7, 88.9)
PMB1672 (A15)	Before Dose 1	166	22.9 (16.7, 30.0)
	Dose 2	165	89.1 (83.3, 93.4)
PMB1989 (A19)	Before Dose 1	167	5.4 (2.5, 10.0)
	Dose 2	167	90.4 (84.9, 94.4)
PMB1256 (B03)	Before Dose 1	172	3.5 (1.3, 7.4)
	Dose 2	164	74.4 (67.0, 80.9)
PMB866 (B09)	Before Dose 1	171	9.9 (5.9, 15.4)
	Dose 2	166	71.1

		166	(63.6, 77.8)
PMB431 (B15)	Before Dose 1	172	6.4 (3.2, 11.2)
	Dose 2	167	85.0 (78.7, 90.1)
PMB648 (B16)	Before Dose 1	172	8.1 (4.5, 13.3)
	Dose 2	164	77.4 (70.3, 83.6)

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.

* The evaluable immunogenicity population was used for the analysis.
† Study 1057: NCT03135834.
‡ For the second dose, serum was obtained approximately 1 month after vaccination.
§ N=number of subjects with valid and determinate hSBA titers for the given strain. U.S. subjects constituted approximately 80% of the total subjects evaluated for immunogenicity.
¶ Exact 2-sided confidence interval (Clopper and Pearson) based upon the observed proportion of subjects.

The hSBA responses to each of the primary strains observed in U.S. subjects after the third dose of Trumenba are presented for Study 1009 and Study 1016 in Table 9.

Table 9: Percentages of U.S. Subjects 10 through 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 1009 and 1016)*,†,‡,§

		Study 1009 (10 through 18 Years of Age)		Study 1016 (18 through 25 Years of Age)	
		N¶	% (95% CI)#	N¶	% (95% CI)#
fHbp Variantᵖ					
≥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		88.3		79.3

		555	(85.3, 90.8)	643	(76.0, 82.4)
Composite hSBA Responseß					
	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 ≥ LOD and < LLOQ, a response is defined as an hSBA titer ≥4 times the LLOQ. (3) For subjects with a baseline hSBA titer ≥ LLOQ, a response is defined as an hSBA titer ≥4 times the baseline titer.

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. For Study 1009 pre-specified criteria for the lower bound of the 95% CI for 4-fold rise in titer were set at 75%, 85%, 65%, and 60%, respectively, for A22, A56, B24 and B44, and 75% for the composite hSBA response for all four primary test strains. For Study 1016 pre-specified criteria for the lower bound of the 95% CI for 4-fold rise in titer were set at 55%, 85%, 50%, and 60%, respectively, for A22, A56, B24, and B44, and 60% for the composite hSBA response for all four primary test strains.

* Evaluable immunogenicity population.
† Study 1009: NCT01830855, and Study 1016: NCT01352845.
‡ Study 1009: Group 1 (0, 2, and 6 months).
§ Study 1016: Group 1 (0, 2, and 6 months).
¶ For ≥4-fold increase, N=number of subjects with valid and determinate hSBA titers for the given strain at both the specified time point and baseline. For composite hSBA response, N=number of subjects with valid and determinate hSBA results on all 4 strains at the given time point.
# Exact 2-sided confidence interval (Clopper-Pearson method) based upon the observed proportion of subjects.
Þ For the third dose, serum was obtained approximately 1 month after vaccination.
ß Composite response = hSBA ≥ LLOQ for all 4 primary meningococcal B strains.

The hSBA responses after the third dose of Trumenba against a panel of 10 additional strains representing the diversity of meningococcal fHbp types prevalent among strains circulating in the U.S. are presented for Study 1009, and Study 1016 in Table10.

Table 10. Percentages of U.S. Subjects 10 through 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 1009 and Study 1016)*,†

	Study 1009	Study 1016
	(10 through 18 Years of Age)	(18 through 25 Years of Age)

fHbp Variant‡		N§	% (95% CI)¶	N§	% (95% CI)¶
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)
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)
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)
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)
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		27.8		33.1

		180	(21.4, 34.9)	163	(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.

* The evaluable immunogenicity population was used for the analysis.
† Study 1009: NCT01830855 and Study 1016 NCT01352845.
‡ For the third dose, serum was obtained approximately 1 month after vaccination.
§ N=number of subjects with valid and determinate hSBA titers for the given strain.
¶ Exact 2-sided confidence interval (Clopper and Pearson) based upon the observed proportion of subjects.

In Study 1012, 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 11.

Table 11: Percentages of European Subjects 11 through 18 Years of Age With a ≥4-Fold Increase in hSBA Titer and Composite Response[*,†] (Study 1012)

	Group 1	**Group 2**	**Group 3**
	3-Dose Schedule (0, 1, and 6 Months)[‡]	**3-Dose Schedule (0, 2, and 6 Months)[§]**	**2-Dose Schedule (0 and 6 Months)[¶]**
fHbp Variant[#]	**% (95% CI)[Þ]**	**% (95% CI)[Þ]**	**% (95% CI)[Þ]**
≥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 Responseß			
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 ≥ LOD and < LLOQ, a response is defined as an hSBA titer ≥4 times the LLOQ. (3) For subjects with a baseline hSBA titer ≥ LLOQ, a response is defined as an hSBA titer ≥4 times the baseline titer.

* Per-schedule Evaluable populations. Dose 2 data include subjects who received two doses, irrespective of whether they received the third dose.
† Study1012: NCT01299480.
‡ 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.
§ 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.
¶ Group 3 (0 and 6 months). The denominators ranged from 188 to 203 after Dose 2, depending on the strain.
# For the second and third doses, serum was obtained approximately 1 month after vaccination.
Þ Exact 2-sided confidence interval (Clopper and Pearson) based upon the observed proportion of subjects.
ß Composite response = hSBA ≥LLOQ for all 4 primary meningococcal B strains.

14.2 Concomitant Vaccine Administration

Study B1971011 (Study 1011) 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 through 17 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 1 month after the third HPV4 vaccination

Study B1971015 (Study 1015) evaluated the immunogenicity of concomitantly administered Trumenba and Meningococcal (Serogroups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (MenACWY) (Sanofi Pasteur Inc.) and Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) (Sanofi Pasteur Ltd.) vaccines. U.S. subjects 10 through 12 years of age were randomized into three groups: Group 1 received Trumenba at 0, 2, and 6 months, and MenACWY and Tdap were coadministered with the first Trumenba dose (N=883). Group 2 received saline at 0, 2 and 6 months, and MenACWY 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 MenACWY 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 MenACWY 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.

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).

Pfizer

Manufactured by
Wyeth Pharmaceuticals LLC
A subsidiary of Pfizer Inc.
Philadelphia, PA 19101

U.S. Govt. License No. 3

LAB-0722-12.0

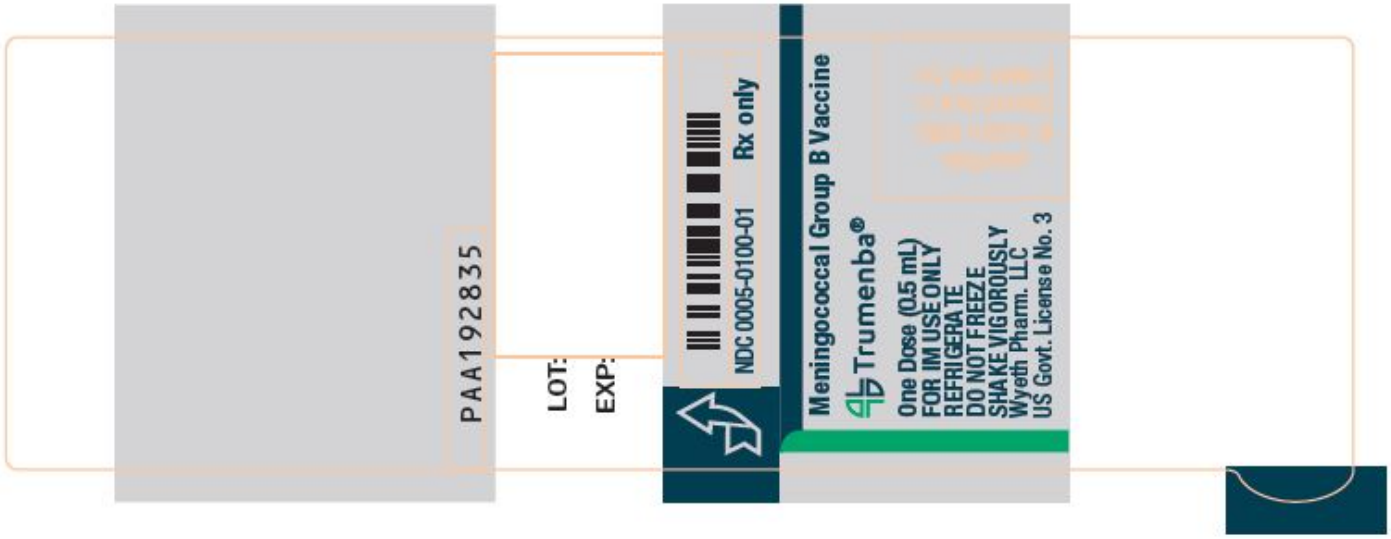
PRINCIPAL DISPLAY PANEL - 0.5 mL Syringe Label

NDC 0005-0100-01
Rx only

Meningococcal
Group B Vaccine

Trumenba®

One Dose (0.5 mL)
FOR IM USE ONLY
REFRIGERATE
DO NOT FREEZE
SHAKE VIGOROUSLY
Wyeth Pharm. LLC
US Govt. License No. 3



PRINCIPAL DISPLAY PANEL - 5 - 0.5 mL Syringe Carton

NDC 0005-0100-05

Meningococcal
Group B Vaccine

Trumenba®

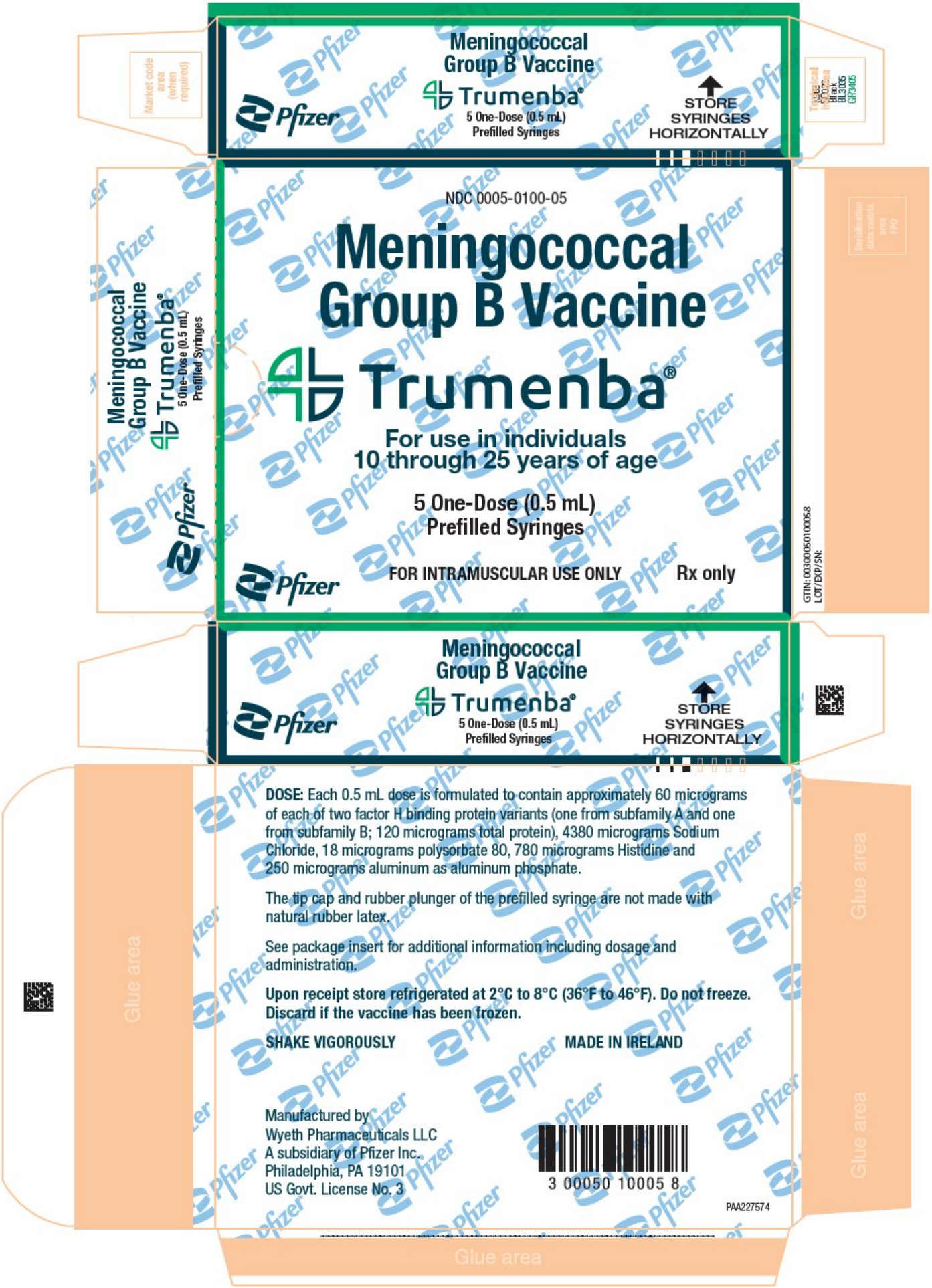
For use in individuals
10 through 25 years of age

5 One-Dose (0.5 mL)
Prefilled Syringes

FOR INTRAMUSCULAR USE ONLY

Pfizer

Rx only


Meningococcal
Group B Vaccine
Trumenba®
5 One-Dose (0.5 mL)
Prefilled Syringes
STORE
SYRINGES
HORIZONTALLY
NDC 0005-0100-05
Meningococcal
Group B Vaccine
Trumenba®
For use in individuals
10 through 25 years of age
5 One-Dose (0.5 mL)
Prefilled Syringes
FOR INTRAMUSCULAR USE ONLY
Rx only
Pfizer
GTIN: 00300050100058
LOT/EXP/SN:
DOSE: Each 0.5 mL dose is formulated to contain approximately 60 micrograms of each of two factor H binding protein variants (one from subfamily A and one from subfamily B; 120 micrograms total protein), 4380 micrograms Sodium Chloride, 18 micrograms polysorbate 80, 780 micrograms Histidine and 250 micrograms aluminum as aluminum phosphate.
The tip cap and rubber plunger of the prefilled syringe are not made with natural rubber latex.
See package insert for additional information including dosage and administration.
Upon receipt store refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze. Discard if the vaccine has been frozen.
SHAKE VIGOROUSLY
MADE IN IRELAND
Manufactured by
Wyeth Pharmaceuticals LLC
A subsidiary of Pfizer Inc.
Philadelphia, PA 19101
US Govt. License No. 3
3 00050 10005 8
PAA227574
Glue area

PRINCIPAL DISPLAY PANEL - 10 - 0.5 mL Syringe Carton

NDC 0005-0100-10

Meningococcal
Group B Vaccine

Trumenba®

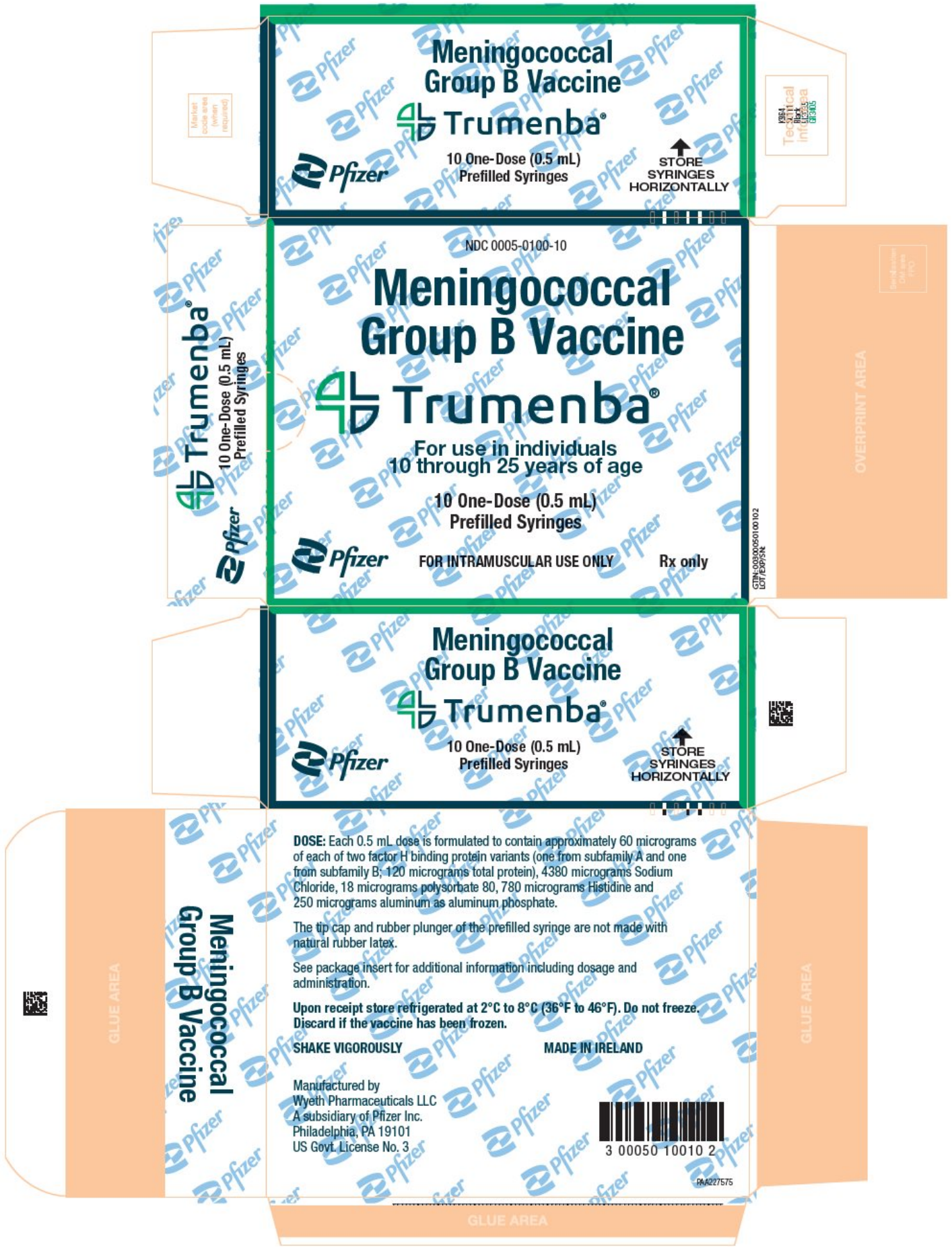
For use in individuals
10 through 25 years of age

10 One-Dose (0.5 mL)
Prefilled Syringes

FOR INTRAMUSCULAR USE ONLY

Pfizer

Rx only


Meningococcal
Group B Vaccine
Trumenba®
Pfizer
10 One-Dose (0.5 mL)
Prefilled Syringes
STORE
SYRINGES
HORIZONTALLY
NDC 0005-0100-10
Meningococcal
Group B Vaccine
Trumenba®
For use in individuals
10 through 25 years of age
10 One-Dose (0.5 mL)
Prefilled Syringes
FOR INTRAMUSCULAR USE ONLY
Rx only
OVERPRINT AREA
GLUE AREA
DOSE: Each 0.5 mL dose is formulated to contain approximately 60 micrograms of each of two factor H binding protein variants (one from subfamily A and one from subfamily B; 120 micrograms total protein), 4380 micrograms Sodium Chloride, 18 micrograms polysorbate 80, 780 micrograms Histidine and 250 micrograms aluminum as aluminum phosphate.
The tip cap and rubber plunger of the prefilled syringe are not made with natural rubber latex.
See package insert for additional information including dosage and administration.
Upon receipt store refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze. Discard if the vaccine has been frozen.
SHAKE VIGOROUSLY
MADE IN IRELAND
Manufactured by
Wyeth Pharmaceuticals LLC
A subsidiary of Pfizer Inc.
Philadelphia, PA 19101
US Govt. License No. 3
3 00050 10010 2
PAA227575

TRUMENBA

meningococcal group b vaccine injection, suspension

Product Information

Product Type	VACCINE	**Item Code (Source)**	NDC:0005-0100
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NEISSERIA MENINGITIDIS GROUP B RECOMBINANT LP2086 A05 PROTEIN VARIANT ANTIGEN (UNII: 583WCD0IZI) (NEISSERIA MENINGITIDIS GROUP B RECOMBINANT LP2086 A05 PROTEIN VARIANT ANTIGEN - UNII:583WCD0IZI)	NEISSERIA MENINGITIDIS GROUP B RECOMBINANT LP2086 A05 PROTEIN VARIANT ANTIGEN	60 ug in 0.5 mL
NEISSERIA MENINGITIDIS GROUP B RECOMBINANT LP2086 B01 PROTEIN VARIANT ANTIGEN (UNII: 7MBD4K530D) (NEISSERIA MENINGITIDIS GROUP B RECOMBINANT LP2086 B01 PROTEIN VARIANT ANTIGEN - UNII:7MBD4K530D)	NEISSERIA MENINGITIDIS GROUP B RECOMBINANT LP2086 B01 PROTEIN VARIANT ANTIGEN	60 ug in 0.5 mL

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	0.018 mg in 0.5 mL
ALUMINUM PHOSPHATE (UNII: F92V3S521O)	0.25 mg in 0.5 mL
HISTIDINE (UNII: 4QD397987E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0005-0100-05	5 in 1 CARTON		
1	NDC:0005-0100-01	0.5 mL in 1 SYRINGE; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		
2	NDC:0005-0100-10	10 in 1 CARTON		
2	NDC:0005-0100-01	0.5 mL in 1 SYRINGE; Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA125549	11/05/2014	

Labeler - Wyeth Pharmaceutical Division of Wyeth Holdings LLC (054065909)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Ireland Pharmaceuticals Unlimited Company		985586408	ANALYSIS(0005-0100) , MANUFACTURE(0005-0100) , API MANUFACTURE(0005-0100)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Health AB		354433591	ANALYSIS(0005-0100) , API MANUFACTURE(0005-0100)

Establishment

Name	Address	ID/FEI	Business Operations
Pfizer Manufacturing Belgium NV		370156507	LABEL(0005-0100)

Establishment

Name	Address	ID/FEI	Business Operations
Wyeth Pharmaceutical Division of Wyeth Holdings LLC		883534067	API MANUFACTURE(0005-0100) , ANALYSIS(0005-0100)