TRUMENBA

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Please click on either of the following links to access the required information:

1. NAME OF THE MEDICINAL PRODUCT

Trumenba

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 ml) contains:

MnB rLP2086 subfamily A	60 µg
MnB rLP2086 subfamily B	60 µg

Excipients with known effect:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
The vaccine is a homogeneous white suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Trumenba is indicated in individuals 10 years and older for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B.

See section 5.1 for information on protection against specific serogroup B strains.

Dosing of Trumenba should be determined taking into consideration the risk of invasive meningococcal B disease by each country or region. The use of this vaccine should be in accordance with official recommendations.

4.2. Posology and method of administration

Posology

Standard schedule for routine immunization: Administer 0.5 ml at 0 and 6 months.

Schedule for individuals at increased risk of invasive meningococcal disease: Administer 2 doses of 0.5 ml at least 1 month apart, followed by a third dose at least 4 months after the second dose.

Booster Dose

A booster dose should be considered following either dosing regimen for individuals at continued risk of invasive meningococcal disease (see section 5.1).

Pediatric Population

Safety and efficacy of Trumenba in children below the age of 10 years of age have not been established.

Elderly

Trumenba has not been studied in adults older than 65 years of age.

Method of administration

For intramuscular injection only. The preferred site for injection is the deltoid muscle of the upper arm.

Separate injection sites and different syringes must be used if more than one vaccine is administered at the same time.

There are no data available on the interchangeability of Trumenba with other meningococcal serogroup B vaccines to complete the vaccination series.

4.3. Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
Severe allergic reaction (e.g., anaphylaxis) after any previous dose of Trumenba or to any component of this vaccine.

4.4. Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine. Do not inject intravenously, intradermally, or subcutaneously.

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

Vaccination should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, should not result in the deferral of vaccination.

As with any intramuscular vaccine, Trumenba should be given with caution to individuals with thrombocytopenia or any coagulation disorder or to those receiving anticoagulant therapy, unless the potential benefit clearly outweighs the risk of administration.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Trumenba.

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 *Neisseria meningitidis* serogroup B even if they develop antibodies following vaccination with Trumenba.

As with any vaccine, vaccination with Trumenba may not protect all vaccine recipients.

4.5. Interaction with other medicinal products and other forms of interaction

Trumenba can be given concomitantly with any of the following vaccines: Reduced Diphtheria Toxoid, Tetanus Toxoid, Acellular Pertussis and Inactivated Poliovirus Vaccine (dTaP-IPV), Quadrivalent Human Papillomavirus vaccine (HPV4), Meningococcal Serogroups A, C, W, Y conjugate vaccine (MenACWY) and Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap).

Do not mix Trumenba with other vaccines or products in the same syringe.

Individuals with impaired immune responsiveness due to the use of immunosuppressive therapy (including irradiation, corticosteroids, antimetabolites, alkylating agents, and cytotoxic agents) may not

respond optimally to active immunization with Trumenba.

4.6. Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of Trumenba vaccine in pregnant women. Therefore, Trumenba should be used during pregnancy only if clearly needed (see section 5.3).

Lactation

It is unknown whether Trumenba is excreted in human milk.

Trumenba should only be used during breast-feeding when the possible advantages outweigh the potential risks.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to fertility in females (see section 5.3).

4.7. Effects on ability to drive and use machines

Trumenba has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

The safety of Trumenba was investigated in clinical studies that enrolled over 23,000 subjects, of which approximately 17,000 subjects received at least one dose of Trumenba administered alone or concomitantly with a licensed vaccine and over 6,000 control subjects received either saline alone, a licensed vaccine alone, or saline and a licensed vaccine.

Adverse reactions reported in clinical studies are listed in this section per system organ class, in decreasing order of seriousness.

Adverse reactions following booster vaccination in 301 subjects aged 15 to 23 years were similar to adverse reactions during the primary Trumenba vaccination series approximately 4 years earlier.

Table 1. ADRs by SOC and CIOMS Frequency Category Listed in Order of Decreasing Medical Seriousness or Clinical Importance within Each Frequency Category and SOC.

System Organ Class	Very Common ≥1/10	Common ≥1/100 to <1/10	Uncommon ≥1/1,000 to <1/100	Rare ≥1/10,000 to <1/1,000	Very Rare <1/10,000	Frequency Not Known (Cannot Be Estimated from the Available Data)
Immune system disorders						Allergic reactions*
Nervous system disorders	Headache					Syncope (fainting)*
Gastrointestinal disorders	Diarrhea; nausea	Vomiting				

Musculoskeletal and connective tissue disorders	Muscle pain (myalgia); joint pain (arthralgia)					
General disorders and administration site conditions	Fatigue; chills; injection site pain; injection site swelling (induration); injection site redness (erythema)	Fever ≥38°C (pyrexia)				

*ADR identified post-marketing

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9. Overdose

Experience of overdose is limited. Overdose with Trumenba is unlikely because it is provided in a prefilled syringe.

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: vaccines

Refer to the current ATC code index for the appropriate code assignment for the pharmacologic and/or therapeutic class.

Mechanism of action

Protection against invasive meningococcal disease is mediated by serum bactericidal antibodies to bacterial surface antigens. Bactericidal antibodies act in concert with human complement to kill meningococci. This process is measured *in vitro* with serum bactericidal assay using human complement (hSBA) for serogroup B. A positive response in SBA is an accepted correlate of protection from meningococcal disease.

Trumenba [bivalent rLP2086] is a vaccine composed of two recombinant lipidated factor H binding proteins (fHbps) and prevents serogroup B disease by inducing broadly protective bactericidal antibody responses against epidemiologically diverse serogroup B strains. fHbp is found on the surface of meningococcal bacteria and is essential for bacteria to avoid host immune defenses. fHbps segregate into two immunologically distinct subfamilies, A and B, and >95% of serogroup B strains express fHbps from either subfamily.

Vaccination with Trumenba, which contains one fHbp each from subfamily A and B, elicits bactericidal antibodies directed against fHbp found on the surface of *N. meningitidis* serogroup B strains.

Clinical efficacy

The efficacy of Trumenba has not been evaluated through clinical trials. Vaccine efficacy has been inferred by demonstrating the induction of serum bactericidal antibody responses to four meningococcal serogroup B test strains (see the Immunogenicity section). The four test strains express fHbp variants representing the two subfamilies (A and B) and, when taken together, are representative of prevalent strains causing invasive disease. The studies assessed the proportions of subjects with a response (hSBA titer of at least 1:8 or 1:16 depending on the hSBA strain), the proportions of subjects with a 4-fold or greater increase from baseline in hSBA titer for each of the four strains and the composite response (a response for the four hSBA strains combined). The studies also assessed the proportion of subjects achieving a defined hSBA titer against a panel of 10 additional strains, each expressing a different fHbp variant. These additional hSBAs support and extend the breadth of vaccine coverage demonstrated by the 4 representative primary strains.

Immunogenicity

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 to 25 years of age in the United States (US) and Europe (Study B1971057 [Study 1057]);
- Following the three-dose schedule (0, 2, and 6 months) in subjects 10 to 25 years of age globally (Studies B1971009 [Study 1009] and B1971016 [Study 1016]);
- Following the two-dose (0 and 6 months) and three-dose schedules (0, 1-2, and 6 months) in subjects 11 to 18 years of age in Europe (Study B1971012 [Study 1012]).

Study 1057 is a Phase 3, randomized, active-controlled, observer-blinded, multicenter trial in which subjects received Trumenba at 0 and 6 months (Trumenba was coadministered with MenACWY-CRM for the first dose) or an investigational pentavalent meningococcal vaccine at 0 and 6 months. The hSBA responses to four test strains observed after the second dose of Trumenba are presented in Table 2.

Table 2. Immune Responses Among Subjects 10 to 25 Years of Age 1 Month Following the Second Dose of Trumenba Given on a 0- and 6-Month Schedule (Study 1057)[a,b]

hSBA Strain (fHbp Variant)[c]		**N**	**% (95% CI)[d]**
PMB80 (A22)	**% hSBA ≥1:16**		
		852	91.0 (88.8, 92.8)
	≥4-Fold rise in hSBA titer (%)		
		827	73.8 (70.6, 76.7)
	hSBA GMT		
	Before Dose 1	839	10.7 (10.3, 11.1)
	Dose 2	852	49.3 (46.2, 52.6)
PMB2001 (A56)	**% hSBA ≥1:8**		
		854	99.4 (98.6, 99.8)
	≥4-Fold rise in hSBA titer (%)		
		823	95.0 (93.3, 96.4)
	hSBA GMT		
	Before Dose 1	833	5.3 (5.0, 5.6)
	Dose 2	854	139.5 (130.6, 149.1)

Table 2. Immune Responses Among Subjects 10 to 25 Years of Age 1 Month Following the Second Dose of Trumenba Given on a 0- and 6-Month Schedule (Study 1057)[a,b]			
hSBA Strain (fHbp Variant)[c]		**N**	**% (95% CI)[d]**
PMB2948 (B24)	**% hSBA ≥1:8**		
		842	79.3 (76.4, 82.0)
	≥4-Fold rise in hSBA titer (%)		
		835	67.4 (64.1, 70.6)
	hSBA GMT		
	Before Dose 1	855	4.9 (4.7, 5.1)
	Dose 2	842	21.2 (19.6, 22.9)
PMB2707 (B44)	**% hSBA ≥1:8**		
		853	94.5 (92.7, 95.9)
	≥4-Fold rise in hSBA titer (%)		
		850	86.4 (83.9, 88.6)
	hSBA GMT		
	Before Dose 1	861	4.3 (4.2, 4.5)
	Dose 2	853	37.8 (35.1, 40.8)
Composite response[e]			
	Before Dose 1	799	1.8 (1.0, 2.9)
	Dose 2	814	74.3 (71.2, 77.3)

Abbreviations: fHbp = factor H binding protein; GMT = geometric mean titer; hSBA = serum bactericidal assay using human complement; LLOQ = lower limit of quantitation; LOD = limit of detection.
Note: The LLOQ is an hSBA titer = 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 (LOD), a 4-fold response 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.

a Evaluable immunogenicity population.
b NCT03135834.
c For the second dose, serum was obtained approximately 1 month after vaccination.
d Exact 2-sided confidence interval (Clopper-Pearson method) based upon the observed proportion of subjects. For GMTs, CIs are obtained by exponentiating the limits of CIs for the mean logarithm of the hSBA titers (based on the Student t distribution).
e Composite response = hSBA ≥LLOQ for all 4 primary meningococcal B strains.

The proportion of subjects achieving a defined hSBA titer after 2 doses of Trumenba, administered on a 0- and 6-month schedule, was evaluated against a panel of 10 additional strains, each expressing a different fHbp variant (Table 3).

Table 3. Immune Responses Among Subjects 10 to 25 Years of Age Against 10 Additional Strains 1 Month Following the Second Dose of Trumenba Given on a 0- and 6-Month Schedule (Study 1057)[a,b]		
	N	**% (95% CI)[d]**
hSBA Strain (fHbp Variant)[c]		
% hSBA ≥1:8		
PMB3040 (A07)	157	96.8 (92.7, 99.0)
PMB1672 (A15)	165	89.1 (83.3, 93.4)
PMB3175 (A29)	166	95.2 (90.7, 97.9)
PMB1256 (B03)	164	74.4 (67.0, 80.9)
PMB866 (B09)	166	71.1 (63.6, 77.8)
PMB431 (B15)	167	85.0 (78.7, 90.1)
PMB648 (B16)	164	77.4 (70.3, 83.6)
% hSBA ≥ 1:16		
PMB3010 (A06)	159	89.3 (83.4, 93.6)
PMB824 (A12)	157	83.4 (76.7, 88.9)
PMB1989 (A19)	167	90.4 (84.9, 94.4)

Abbreviations: fHbp = factor H binding protein; hSBA = serum bactericidal assay using human complement; LLOQ = lower limit of quantitation.
Note: The LLOQ is an hSBA titer = 1:16 for A06, A12, and A19; 1:8 for A07, A15, A29, B03, B09, B15, and B16.
a Evaluable immunogenicity population.
b NCT03135834.
c For second dose, serum was obtained approximately 1 month after vaccination.
d Exact 2-sided confidence interval (Clopper and Pearson) based upon the observed proportion of subjects.

Study 1009 was a Phase 3, randomized, active-controlled, observer-blinded, multicenter trial in which subjects aged 10 to 18 years received 1 of 3 lots (Groups 1, 2, and 3) of Trumenba or the active control hepatitis A virus (HAV) vaccine/saline (Group 4). The study assessed the safety, tolerability, immunogenicity, and demonstration of manufacturability of 3 lots of Trumenba administered on a 0-, 2-, and 6-month schedule. The hSBA responses to four test strains observed after the third dose in Group 1 and 4 are presented in Table 4. Results from Groups 2 and 3 are not presented, as only 2 representative strains were evaluated. Similar results were observed in Groups 2 and 3 as observed in Group 1.

Study 1016 was a Phase 3, randomized, placebo-controlled, observer-blinded, multicenter trial in which subjects 18 to 25 years of age were assigned to 2 groups in a 3:1 ratio (Group 1: Group 2). Group 1 received Trumenba at months 0, 2, and 6. Group 2 received saline at months 0, 2, and 6. The hSBA responses to four test strains observed after the third dose in Group 1 and 2 are presented in Table 4.

Table 4. Immune Responses Among Subjects 10 to 25 Years of Age 1 Month Following the Third Dose of Trumenba or Control Given on a 0-, 2-, and 6-Month Schedule (Study 1009 and Study 1016)[a,b]

		Study 1009 (10-18 years of age)				Study 1016 (18-25 years of age)			
		Group 1		Group 4		Group 1		Group 2	
		Trumenba		HAV/saline		Trumenba		Saline	
hSBA Strain (fHbp Variant)[c]		**N**	**% (95% CI)[d]**	**N**	**% (95% CI)[d]**	**N**	**% (95% CI)[d]**	**N**	**% (95% CI)[d]**
PMB80 (A22)	**% hSBA ≥1:16**								
		1,266	97.8 (96.8, 98.5)	749	34.0 (30.7, 37.6)	1,714	93.5 (92.2, 94.6)	577	36.6 (32.6, 40.6)
	≥4-fold rise in hSBA titer (%)								
		1,225	83.2 (81.0, 85.2)	730	9.6 (7.6, 12.0)	1,695	80.5 (78.6, 82.4)	568	6.3 (4.5, 8.7)
	hSBA GMT								
	Before Dose 1	1,238	12.6 (12.1, 13.1)	748	13.4 (12.6, 14.1)	1,704	12.8 (12.3, 13.3)	573	13.0 (12.2, 13.9)
	Dose 3	1,266	86.8 (82.3, 91.5)	749	12.6 (12.0, 13.4)	1,714	74.3 (70.2, 78.6)	577	13.2 (12.4, 14.1)
PMB2001 (A56)	**% hSBA ≥1:8**								
		1,229	99.5 (98.9, 99.8)	363	27.5 (23.0, 32.5)	1,708	99.4 (98.9, 99.7)	552	34.2 (30.3, 38.4)
	≥4-fold rise in hSBA titer (%)								
		1,128	90.2 (88.4, 91.9)	337	11.3 (8.1, 15.1)	1,642	90.0 (88.4, 91.4)	533	10.3 (7.9, 13.2)
	hSBA GMT								
	Before Dose 1	1,135	8.4 (7.8, 9.1)	362	8.3 (7.2, 9.5)	1,657	8.8 (8.3, 9.3)	563	9.2 (8.3, 10.3)
	Dose 3	1,229	222.5 (210.1, 235.6)	363	8.8 (7.6, 10.1)	1,708	176.7 (167.8, 186.1)	552	9.1 (8.2, 10.1)
PMB2948 (B24)	**% hSBA ≥1:8**								
		1,250	87.1 (85.1, 88.9)	762	7.0 (5.3, 9.0)	1,702	95.1 (93.9, 96.0)	573	30.2 (26.5, 34.1)
	≥4-fold rise in hSBA titer (%)								
		1,235	79.8 (77.4, 82.0)	752	2.7 (1.6, 4.1)	1,675	79.3 (77.3, 81.2)	562	5.5 (3.8, 7.7)
	hSBA GMT								
	Before Dose 1	1,264	4.5 (4.4, 4.6)	758	4.6 (4.4, 4.8)	1,696	7.6 (7.3, 8.0)	570	7.6 (7.0, 8.3)
	Dose 3	1,250	24.1 (22.7, 25.5)	762	4.5 (4.4, 4.7)	1,702	49.5 (46.8, 52.4)	573	7.2 (6.6, 7.8)
PMB2707 (B44)	**% hSBA ≥1:8**								
		1,210	89.3 (87.4, 90.9)	393	5.3 (3.3, 8.1)	1,703	87.4 (85.8, 89.0)	577	11.4 (9.0, 14.3)
	≥4-fold rise in hSBA titer (%)								
		1,203	85.9 (83.8, 87.8)	391	1.0 (0.3, 2.6)	1,696	79.6 (77.6, 81.5)	573	1.6 (0.7, 3.0)
	hSBA GMT								
	Before Dose 1	1,230	4.3 (4.2, 4.3)	391	4.3 (4.2, 4.5)	1,716	4.8 (4.7, 4.9)	578	4.8 (4.6, 5.1)
	Dose 3	1,210	50.9 (47.0, 55.2)	393	4.4 (4.2, 4.6)	1,703	47.6 (44.2, 51.3)	577	4.8 (4.6, 5.1)
Composite response[e]									
	Before Dose 1	1,088	1.1 (0.6, 1.9)	354	2.0 (0.8, 4.0)	1,612	7.3 (6.0, 8.6)	541	6.1 (4.2, 8.5)
	Dose 3	1,170	83.5 (81.3, 85.6)	353	2.8 (1.4, 5.1)	1,664	84.9 (83.1, 86.6)	535	7.5 (5.4, 10.0)

Table 4. Immune Responses Among Subjects 10 to 25 Years of Age 1 Month Following the Third Dose of Trumenba or Control Given on a 0-, 2-, and 6-Month Schedule (Study 1009 and Study 1016)[a,b]

	Study 1009 (10-18 years of age)		Study 1016 (18-25 years of age)	
	Group 1	Group 4	Group 1	Group 2
	Trumenba	HAV/saline	Trumenba	Saline

Abbreviations: fHbp = factor H binding protein; GMT = geometric mean titer; hSBA = serum bactericidal assay using human complement; LLOQ = lower limit of quantitation; LOD = limit of detection.
Note: The LLOQ is an hSBA titer = 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 (LOD), a 4-fold response 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.
a Evaluable immunogenicity population.
b Study 1009 = NCT01830855 and Study 1016 = NCT01352845.
c For the third dose, serum was obtained approximately 1 month after vaccination.
d Exact 2-sided confidence interval (Clopper-Pearson method) based upon the observed proportion of subjects. For GMTs, CIs are obtained by exponentiating the limits of CIs for the mean logarithm of the hSBA titers (based on the Student t distribution).
e Composite response = hSBA ≥LLOQ for all 4 primary meningococcal B strains.

In Studies 1009 and 1016, the proportion of subjects achieving a defined hSBA titer after 3 doses of Trumenba, administered on a 0-, 2-, and 6-month schedule, was evaluated against a panel of 10 additional strains, each expressing a different fHbp variant (Table 5).

Table 5. Immune Responses Among Subjects 10 to 25 Years of Age Against 10 Additional Strains 1 Month Following the Third Dose of Trumenba Given on a 0-, 2-, and 6-Month Schedule (Study 1009 and Study 1016)[a,b]

	Study 1009 (10 to 18 Years of Age)		Study 1016 (18 to 25 Years of Age)	
	N	% (95% CI)[d]	N	% (95% CI)[d]
hSBA Strain (fHbp Variant)[c]				
% hSBA ≥1:8				
PMB3040 (A07)	280	96.4 (93.5, 98.3)	277	95.7 (92.6, 97.7)
PMB1672 (A15)	266	87.2 (82.6, 91.0)	279	91.8 (87.9, 94.7)
PMB3175 (A29)	278	98.6 (96.4, 99.6)	283	99.3 (97.5, 99.9)
PMB1256 (B03)	279	92.5 (88.7, 95.3)	273	86.4 (81.8, 90.3)
PMB866 (B09)	276	86.2 (81.6, 90.1)	274	77.0 (71.6, 81.9)
PMB431 (B15)	281	98.2 (95.9, 99.4)	276	96.7 (93.9, 98.5)
PMB648 (B16)	278	81.7 (76.6, 86.0)	273	78.0 (72.6, 82.8)
% hSBA ≥1:16				
PMB3010 (A06)	280	95.7 (92.6, 97.8)	275	92.0 (88.1, 94.9)
PMB824 (A12)	277	75.1 (69.6, 80.1)	275	71.3 (65.5, 76.5)
PMB1989 (A19)	275	92.7 (89.0, 95.5)	284	95.8 (92.7, 97.8)

Abbreviations: fHbp = factor H binding protein; hSBA = serum bactericidal assay using human complement; LLOQ = lower limit of quantitation.
Note: The LLOQ is an hSBA titer = 1:16 for A06, A12, and A19; 1:8 for A07, A15, A29, B03, B09, B15, and B16.
a Evaluable immunogenicity population.

Table 5. Immune Responses Among Subjects 10 to 25 Years of Age Against 10 Additional Strains 1 Month Following the Third Dose of Trumenba Given on a 0-, 2-, and 6-Month Schedule (Study 1009 and Study 1016)[a,b]				
	Study 1009 (10 to 18 Years of Age)		Study 1016 (18 to 25 Years of Age)	
	N	% (95% CI)[d]	N	% (95% CI)[d]
b Study 1009 = NCT01830855 and Study 1016 = NCT01352845.				
c For third dose, serum was obtained approximately 1 month after vaccination.				
d Exact 2-sided confidence interval (Clopper and Pearson) based upon the observed proportion of subjects.				

In Study 1012, Trumenba was administered according to the following schedules: Group 1 (0, 1, and 6 months); Group 2 (0, 2, and 6 months); Group 3 (0 and 6 months); Group 4 (0 and 2 months); Group 5 (0 and 4 months) [see section 4.8]. The hSBA responses observed after the second or third dose for Groups 1, 2 and 3 are presented in Table 6.

Table 6. Immune Responses Among Subjects 11 to 18 Years of Age Administered Trumenba After Various 2- and 3-Dose Schedules (Study 1012)[a,b]							
hSBA Strain (fHbp Variant)[c]		**Group 1 (0, 1, and 6 Months)**		**Group 2 (0, 2, and 6 Months)**		**Group 3 (0 and 6 Months)**	
		N	**% or GMT (95% CI)[d]**	**N**	**% or GMT (95% CI)[d]**	**N**	**% or GMT (95% CI)[d]**
PMB80 (A22)	**% hSBA ≥1:16**						
	Dose 2	351	73.5 (68.6, 78.0)	344	88.1 (84.2, 91.3)	369	93.2 (90.2, 95.6)
	Dose 3	360	91.4 (88.0, 94.1)	357	95.0 (92.1, 97.0)	--	--
	≥4-fold rise in hSBA titer (%)						
	Dose 2	343	55.7 (50.3, 61.0)	336	73.8 (68.8, 78.4)	362	80.7 (76.2, 84.6)
	Dose 3	351	78.1 (73.4, 82.3)	349	84.0 (79.7, 87.6)	--	--
	hSBA GMT						
	Before Dose 1	356	11.7 (10.87, 12.58)	352	10.8 (10.10, 11.62)	364	10.8 (10.10, 11.52)
	Dose 2	351	29.0 (26.0, 32.5)	344	35.6 (32.2, 39.4)	369	50.6 (45.9, 55. 8)
	Dose 3	360	58.4 (52.4, 64.9)	357	58.3 (53.2, 63.9)	--	--
PMB2001 (A56)	**% hSBA ≥1:8**						
	Dose 2	353	96.6 (94.1, 98.2)	339	97.9 (95.8, 99.2)	370	98.4 (96.5, 99.4)
	Dose 3	362	99.4 (98.0, 99.9)	359	98.9 (97.2, 99.7)	--	--
	≥4-fold rise in hSBA titer (%)						
	Dose 2	338	86.1 (81.9, 89.6)	327	90.5 (86.8, 93.5)	354	90.4 (86.8, 93.3)
	Dose 3	347	93.4 (90.2, 95.8)	347	94.2 (91.2, 96.4)	--	--
	hSBA GMT						
	Before Dose 1	350	6.8 (6.06, 7.64)	348	6.1 (5.54, 6.77)	355	6.7 (6.00, 7.48)
	Dose 2	353	77.3 (68.5, 87.1)	339	94.6 (84.6, 105.7)	370	125.6 (112.6, 140.2)
	Dose 3	362	152.9 (137.2, 170.5)	359	155.6 (140.4, 172.4)	--	--
PMB2948 (B24)	**% hSBA ≥1:8**						
	Dose 2	344	62.2 (56.9, 67.4)	337	70.3 (65.1, 75.2)	359	81.1 (76.6, 85.0)
	Dose 3	354	89.0 (85.2, 92.0)	354	88.4 (84.6, 91.6)	--	--
	≥4-fold rise in hSBA titer (%)						
	Dose 2	341	47.2 (41.8, 52.7)	333	54.1 (48.5, 59.5)	357	65.5 (60.4, 70.5)
	Dose 3	351	74.6 (69.8, 79.1)	350	75.4 (70.6, 79.8)	--	--
	hSBA GMT						
	Before Dose 1	362	5.3 (4.93, 5.75)	356	5.1 (4.77, 5.52)	369	5.0 (4.70, 5.38)
	Dose 2	344	13.8 (12.2, 15.6)	337	14.9 (13.20, 16.73)	359	20.6 (18.3, 23.2)
	Dose 3	354	29.1 (25.9, 32.7)	354	25.6 (23.0, 28.5)	--	--
	% hSBA ≥1:8						

PMB2707 (B44)	Dose 2	341	54.0 (48.5, 59.3)	331	61.9 (56.5, 67.2)	356	77.5 (72.8, 81.8)
	Dose 3	356	88.5 (84.7, 91.6)	352	86.1 (82.0, 89.5)	--	--
	≥4-fold rise in hSBA titer (%)						
	Dose 2	339	43.4 (38.0, 48.8)	328	55.2 (49.6, 60.6)	355	66.8 (61.6, 71.6)
	Dose 3	354	82.2 (77.8, 86.0)	349	81.7 (77.2, 85.6)	--	--
	hSBA GMT						
	Before Dose 1	363	4.4 (4.18, 4.54)	357	4.5 (4.24, 4.67)	370	4.5 (4.26, 4.70)
	Dose 2	341	13.1 (11.3, 15.1)	331	15.5 (13.5, 17.9)	356	22.5 (19.6, 25.7)
	Dose 3	356	40.3 (35.2, 46.1)	352	35.0 (30.6, 39.9)	--	--
	Composite response[e]						
	Before Dose 1	339	3.5 (1.8, 6.1)	333	2.4 (1.0, 4.7)	345	3.5 (1.8, 6.0)
	Dose 2	308	45.1 (39.5, 50.9)	311	54.3 (48.6, 60.0)	343	73.5 (68.5, 78.1)
	Dose 3	337	83.1 (78.6, 86.9)	345	81.7 (77.3, 85.7)	--	--

Abbreviations: fHbp = factor H binding protein; GMT = geometric mean titer; hSBA = serum bactericidal assay using human complement; LLOQ = lower limit of quantitation; LOD = limit of detection.
Note: The LLOQ is an hSBA titer = 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 (LOD), a 4-fold response 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.
a Evaluable immunogenicity population.
b NCT01299480.
c For the second and third doses, serum was obtained approximately 1 month after vaccination.
d Exact 2-sided confidence interval (Clopper and Pearson) based upon the observed proportion of subjects. For GMTs, CIs are obtained by exponentiating the limits of CIs for the mean logarithm of the hSBA titers (based on the Student t distribution).
e Composite response = hSBA ≥LLOQ for all 4 primary meningococcal B strains.

Limited immunogenicity data is available for subjects 40 years and above.

Concomitant vaccine administration

In Study B1971010 (Study 1010) conducted in Europe, the immunogenicity of dTaP-IPV (a combined low-dose diphtheria, tetanus, acellular pertussis, and inactivated poliomyelitis virus vaccine) given concomitantly with the first dose of Trumenba was evaluated in adolescents 11 to 18 years of age. Noninferiority was demonstrated, as the lower limit of the 2-sided 95% CI for the difference in proportion of responders between the Trumenba + dTaP-IPV group (Group 1) and the dTaP-IPV–alone group (Group 2) 1 month after the dTaP-IPV dose was greater than -0.10 (-10%) for the 9 antigens in dTaP-IPV (i.e., the lowest lower bound of the 95% CI on the proportion difference was -4.7% [pertussis toxoid]).

In Study B1971011 (Study 1011) conducted in the US, the immunogenicity of concomitantly administered Trumenba and HPV4 vaccine was evaluated in adolescents 11 to 17 years of age. Immune responses were evaluated by comparisons of geometric mean titers (GMTs) for each human papillomavirus (HPV) type at 1 month after the third HPV4 vaccination and hSBA GMTs using two meningococcal serogroup B test strains [variants A22 and B24] 1 month after the third vaccination with Trumenba. The noninferiority criteria for comparisons of the GMT ratio (lower limit of the 2-sided 95% confidence interval of the GMT ratio >0.67) were met for three HPV types (6, 11, and 16) and for the

meningococcal serogroup B strains. For HPV-18, the lower bound of the 95% confidence interval (CI) for the GMT ratio was 0.62 at one month after the third HPV4 vaccination. One month after Dose 3 with HPV4, ≥99% of subjects seroconverted to all 4 HPV antigens in both the saline + HPV4 and Trumenba + HPV4 groups.

In Study B1971015 (Study 1015) conducted in the US, the immunogenicity of concomitantly administered Trumenba with meningococcal polysaccharide (serogroups A, C, Y and W 135) diphtheria toxoid conjugate (MenACWY) and Tdap vaccines was evaluated in adolescents 10 to 12 years of age. Immune responses were evaluated by comparisons of GMTs for each of 10 MenACWY and Tdap antigens 1 month after the first vaccination. The criterion for the noninferiority margin of 1.5-fold was met for all MenACWY and Tdap antigens.

Persistence of immunity and response to booster vaccination

Study B1971033 (Study 1033) was an open-label, follow-up study of subjects previously enrolled in a primary study, including Study 1012. Subjects attended visits over 4 years for collection of blood samples and received a single booster dose of Trumenba approximately 4 years after receipt of a primary series of 2 or 3 doses of Trumenba.

The hSBA responses 4 years after the primary series and 26 months after the booster dose for subjects enrolled from primary Study 1012 Group 1 (0, 1, and 6 months), Group 2 (0, 2, and 6 months), and Group 3 (0 and 6 months) are presented in Tables 7 and 8.

Table 7. Persistence of Immune and Booster Responses Among Subjects 11 to 18 Years of Age Administered a Primary Series of Trumenba on a 0-, 1-, and 6-Month-; 0-, 2-, and 6-Month; or 0- and 6-Month Schedule and a Booster 4 Years After Primary Series (Study 1033)[a,b]

hSBA Strain (fHbp Variant) / Time Point		Primary Study 1012 Vaccine Group (as Randomized)					
		Group 1 (0, 1, and 6 Months)		Group 2 (0, 2, and 6 Months)		Group 3 (0 and 6 Months)	
		N	% (95% CI)[c]	N	% (95% CI)[c]	N	% (95% CI)[c]
PMB80 (A22)	**% hSBA ≥1:16**						
	1 Month after last primary dose	59	89.8 (79.2, 96.2)	57	91.2 (80.7, 97.1)	61	98.4 (91.2, 100.0)
	12 Months after last primary dose	99	41.4 (31.6, 51.8)	111	45.0 (35.6, 54.8)	113	36.3 (27.4, 45.9)
	48 Months after last primary dose	59	49.2 (35.9, 62.5)	57	56.1 (42.4, 69.3)	61	55.7 (42.4, 68.5)
	1 Month after booster dose	59	100.0 (93.9, 100.0)	58	100.0 (93.8, 100.0)	60	96.7 (88.5, 99.6)
	12 Months after booster dose	58	74.1 (61.0, 84.7)	54	77.8 (64.4, 88.0)	60	80.0 (67.7, 89.2)
	26 Months after booster dose	0	NE	34	73.5 (55.6, 87.1)	42	61.9 (45.6, 76.4)

Table 7. Persistence of Immune and Booster Responses Among Subjects 11 to 18 Years of Age Administered a Primary Series of Trumenba on a 0-, 1-, and 6-Month-; 0-, 2-, and 6-Month; or 0- and 6-Month Schedule and a Booster 4 Years After Primary Series (Study 1033)[a,b]

hSBA Strain (fHbp Variant)	Time Point	Primary Study 1012 Vaccine Group (as Randomized)					
		Group 1 (0, 1, and 6 Months)		Group 2 (0, 2, and 6 Months)		Group 3 (0 and 6 Months)	
		N	% (95% CI)[c]	N	% (95% CI)[c]	N	% (95% CI)[c]
PMB2001 (A56)	**% hSBA ≥1:8**						
	1 Month after last primary dose	58	100.0 (93.8, 100.0)	57	98.2 (90.6, 100.0)	62	98.4 (91.3, 100.0)
	12 Months after last primary dose	98	73.5 (63.6, 81.9)	109	76.1 (67.0, 83.8)	106	60.4 (50.4, 69.7)
	48 Months after last primary dose	53	43.4 (29.8, 57.7)	55	56.4 (42.3, 69.7)	62	43.5 (31.0, 56.7)
	1 Month after booster dose	57	100.0 (93.7, 100.0)	56	100.0 (93.6, 100.0)	62	98.4 (91.3, 100.0)
	12 Months after booster dose	55	90.9 (80.0, 97.0)	55	89.1 (77.8, 95.9)	59	81.4 (69.1, 90.3)
	26 Months after booster dose	0	NE	29	82.8 (64.2, 94.2)	40	57.5 (40.9, 73.0)
PMB2948 (B24)	**% hSBA ≥1:8**						
	1 Month after last primary dose	59	88.1 (77.1, 95.1)	58	91.4 (81.0, 97.1)	60	85.0 (73.4, 92.9)
	12 Months after last primary dose	98	40.8 (31.0, 51.2)	108	49.1 (39.3, 58.9)	103	36.9 (27.6, 47.0)
	48 Months after last primary dose	59	40.7 (28.1, 54.3)	57	49.1 (35.6, 62.7)	62	40.3 (28.1, 53.6)
	1 Month after booster dose	58	100.0 (93.8, 100.0)	57	100.0 (93.7, 100.0)	62	96.8 (88.8, 99.6)
	12 Months after booster dose	58	65.5 (51.9, 77.5)	54	74.1 (60.3, 85.0)	62	77.4 (65.0, 87.1)
	26 Months after booster dose	0	NE	33	78.8 (61.1, 91.0)	42	59.5 (43.3, 74.4)
PMB2707 (B44)	**% hSBA ≥1:8**						
	1 Month after last primary dose	58	86.2 (74.6, 93.9)	57	89.5 (78.5, 96.0)	60	81.7 (69.6, 90.5)
	12 Months after last primary dose	100	24.0 (16.0, 33.6)	111	22.5 (15.1, 31.4)	115	16.5 (10.3, 24.6)
	48 Months after last primary dose	57	36.8 (24.4, 50.7)	57	35.1 (22.9, 48.9)	62	12.9 (5.7, 23.9)
	1 Month after booster dose	59	100.0 (93.9, 100.0)	58	100.0 (93.8, 100.0)	61	93.4 (84.1, 98.2)
	12 Months after booster dose	56	75.0 (61.6, 85.6)	53	81.1 (68.0, 90.6)	61	59.0 (45.7, 71.4)
	26 Months after booster dose	0	NE	33	66.7 (48.2, 82.0)	43	62.8 (46.7, 77.0)
Composite response[d]							
	1 Month after last primary dose	57	80.7 (68.1, 90.0)	55	87.3 (75.5, 94.7)	57	77.2 (64.2, 87.3)
	12 Months after last primary dose	55	10.9 (4.1, 22.2)	51	13.7 (5.7, 26.3)	49	20.4 (10.2, 34.3)
	48 Months after last primary dose	51	19.6 (9.8, 33.1)	53	30.2 (18.3, 44.3)	61	9.8 (3.7, 20.2)
	1 Month after booster dose	56	100 (93.6, 100.0)	55	100.0 (93.5, 100.0)	59	91.5 (81.3, 97.2)
	12 Months after booster dose	53	52.8 (38.6, 66.7)	48	64.6 (49.5, 77.8)	57	61.4 (47.6, 74.0)

Table 7. Persistence of Immune and Booster Responses Among Subjects 11 to 18 Years of Age Administered a Primary Series of Trumenba on a 0-, 1-, and 6-Month-; 0-, 2-, and 6-Month; or 0- and 6-Month Schedule and a Booster 4 Years After Primary Series (Study 1033)[a,b]

hSBA Strain (fHbp Variant) Time Point		Primary Study 1012 Vaccine Group (as Randomized)					
		Group 1 (0, 1, and 6 Months)		Group 2 (0, 2, and 6 Months)		Group 3 (0 and 6 Months)	
		N	% (95% CI)[c]	N	% (95% CI)[c]	N	% (95% CI)[c]
	26 Months after booster dose	0	NE	27	48.1 (28.7, 68.1)	36	44.4 (27.9, 61.9)

Abbreviations: fHbp = factor H binding protein; hSBA = serum bactericidal assay using human complement; LLOQ = lower limit of quantitation; mITT = modified intent-to-treat; NE = not evaluated (subjects were not followed beyond 12 months post booster).
Note: The LLOQ is an hSBA titer = 1:16 for PMB80 (A22) and 1:8 for PMB2001 (A56), PMB2948 (B24), and PMB2707 (B44).

Note: Serum samples were analyzed concurrently in the same serology campaign for all time points except the 12 months post-primary dose time point for which results are from the interim analysis.

a Booster evaluable immunogenicity population. For 12 months after primary dose, specifically for entries for % hSBA ≥1:8 or 1:16, the analysis population is Stage 1 mITT immunogenicity population.
b NCT01543087.
c Exact 2-sided confidence interval (Clopper and Pearson) based upon the observed proportion of subjects.
d Composite response = hSBA ≥LLOQ for all 4 primary meningococcal B strains.

Table 8. Persistence of Immune and Booster Responses (GMT) Among Subjects 11 to 18 Years of Age Administered a Primary Series of Trumenba on a 0-, 1-, and 6-Month; 0-, 2-, and 6-Month; or 0- and 6-Month Schedule and a Booster 4 Years After Primary Series (Study 1033)[a,b]

hSBA Strain (fHbp Variant) Time Point		Primary Study 1012 Vaccine Group (as Randomized)					
		Group 1 (0, 1, and 6 Months)		Group 2 (0, 2, and 6 Months)		Group 3 (0 and 6 Months)	
		N	GMT (95% CI)[c]	N	GMT (95% CI)[c]	N	GMT (95% CI)[c]
PMB80 (A22)	**hSBA GMT**						
	1 Month after last primary dose	59	53.0 (40.4, 69.6)	57	59.5 (45.5, 77.8)	61	55.8 (46.2, 67.4)
	12 Months after last primary dose	99	14.9 (12.6, 17.7)	111	15.8 (13.4, 18.6)	113	15.6 (13.0, 18.8)
	48 Months after last primary dose	59	16.6 (13.0, 21.1)	57	20.7 (15.6, 27.4)	61	16.6 (13.4, 20.5)
	1 Month after booster dose	59	126.5 (102.7, 155.8)	58	176.7 (137.8, 226.7)	60	142.0 (102.9, 196.1)
	12 Months after booster dose	58	33.6 (24.5, 46.1)	54	44.1 (31.2, 62.4)	60	31.6 (23.5, 42.5)
	26 Months after booster dose	0	NE	34	34.7 (23.0, 52.4)	42	27.1 (18.6, 39.6)
PMB2001 (A56)	**hSBA GMT**						
	1 Month after last primary dose	58	158.7 (121.5,207.3)	57	191.2 (145.8, 250.8)	62	143.1 (109.6, 187.0)
	12 Months after last primary dose	98	25.7 (19.4, 34.0)	109	27.3 (21.0, 35.4)	106	18.5 (13.8, 24.7)
	48 Months after last primary dose	53	10.7 (7.4, 15.3)	55	15.0 (10.2, 22.2)	62	10.8 (7.6, 15.3)
	1 Month after booster dose	57	359.8 (278.7, 464.7)	56	414.8 (298.8, 575.9)	62	313.1 (221.3, 442.8)
	12 Months after booster dose	55	47.3 (34.3, 65.3)	55	64.0 (42.6, 96.2)	59	41.0 (26.7, 62.7)
	26 Months after booster dose	0	NE	29	37.8 (21.3, 67.2)	40	16.0 (9.9, 25.8)
	hSBA GMT						

Table 8. Persistence of Immune and Booster Responses (GMT) Among Subjects 11 to 18 Years of Age Administered a Primary Series of Trumenba on a 0-, 1-, and 6-Month; 0-, 2-, and 6-Month; or 0- and 6-Month Schedule and a Booster 4 Years After Primary Series (Study 1033)[a,b]

hSBA Strain (fHbp Variant)	Time Point	Primary Study 1012 Vaccine Group (as Randomized)					
		Group 1 (0, 1, and 6 Months)		Group 2 (0, 2, and 6 Months)		Group 3 (0 and 6 Months)	
		N	GMT (95% CI)[c]	N	GMT (95% CI)[c]	N	GMT (95% CI)[c]
PMB2948 (B24)	1 Month after last primary dose	59	25.6 (19.7, 33.3)	58	30.5 (23.8, 39.1)	60	29.2 (21.5, 39.6)
	12 Months after last primary dose	98	9.7 (7.5, 12.4)	108	11.5 (9.0, 14.6)	103	8.4 (6.7, 10.6)
	48 Months after last primary dose	59	10.7 (7.6, 15.1)	57	11.4 (8.2, 15.9)	62	8.9 (6.8, 11.8)
	1 Month after booster dose	58	94.9 (74.6, 120.9)	57	101.6 (83.1, 124.2)	62	79.1 (60.6, 103.5)
	12 Months after booster dose	58	21.1 (14.2, 31.3)	54	25.7 (17.7, 37.5)	62	22.4 (16.4, 30.5)
	26 Months after booster dose	0	NE	33	24.4 (16.1, 36.8)	42	14.5 (9.9, 21.3)
PMB2707 (B44)	**hSBA GMT**						
	1 Month after last primary dose	58	46.3 (31.7, 67.8)	57	50.2 (35.3, 71.3)	60	35.5 (24.5, 51.4)
	12 Months after last primary dose	100	6.4 (5.2, 7.8)	111	6.0 (5.1, 7.2)	115	5.6 (4.8, 6.5)
	48 Months after last primary dose	57	8.3 (6.3, 11.0)	57	7.6 (5.8, 10.0)	62	4.6 (4.1, 5.1)
	1 Month after booster Dose	59	137.3 (100.3, 188.0)	58	135.9 (108.0, 171.0)	61	74.2 (51.6, 106.8)
	12 Months after booster dose	56	23.2 (16.2, 33.2)	53	24.3 (17.8, 33.3)	61	13.3 (9.7, 18.3)
	26 Months after booster dose	0	NE	33	16.0 (10.4, 24.7)	43	13.6 (9.8, 18.9)

Abbreviations: fHbp = factor H binding protein; GMT = geometric mean titer; hSBA = serum bactericidal assay using human complement; mITT = modified intent-to-treat; NE = not evaluated (subjects were not followed beyond 12 months post booster).

Note: Serum samples were analyzed concurrently in the same serology campaign for all time points except the 12 months post-primary dose time point for which results are from the interim analysis.

a Booster evaluable immunogenicity population. For 12 months after primary dose, the analysis population is Stage 1 mITT immunogenicity population.

b NCT01543087.

c CIs are obtained by exponentiating the limits of CIs for the mean logarithm of the hSBA titers (based on the Student t distribution).

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Non-clinical data revealed no special hazard for humans based on conventional studies of repeated dose toxicity, local tolerance, and reproduction and developmental toxicity.

Reproduction studies performed in female rabbits at doses equivalent to the highest administered human dose have revealed no evidence of impaired female fertility or harm to the fetus due to Trumenba. Because animal reproductive studies are not always predictive of the human response, this vaccine should be used during pregnancy only if clearly needed. Trumenba has not been evaluated for impairment of fertility in males.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium Chloride
Histidine
Water for Injection
Aluminium Phosphate ($AlPO_4$)
Polysorbate 80

6.2. Incompatibilities

Do not mix Trumenba with other vaccines/products in the same syringe.

6.3. Shelf life

Refer to outer carton for expiration date.

6.4. Special precautions for storage

Store in a refrigerator (2°C-8°C).

Syringes should be stored in the refrigerator horizontally to minimize the re-dispersion time.
Do not freeze. Discard if the vaccine has been frozen.

6.5. Nature and contents of container

0.5 ml suspension in a prefilled syringe made of Type I borosilicate glass with plastic Luer Lok adapter, latex-free chlorobutyl rubber stopper, and a synthetic isoprene bromobutyl rubber tip cap with a plastic rigid tip cap cover with or without needles. The tip cap and rubber plunger do not contain natural rubber latex.

Pack sizes of 1 and 5 prefilled syringes, with or without needle.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

The vaccine should be shaken vigorously to ensure that a homogeneous white suspension is obtained.
Do not use the vaccine if it cannot be re-suspended.

The vaccine should be visually inspected for particulate matter and discoloration prior to administration.
This product should not be used if particulate matter or discoloration is found.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. PRODUCT OWNER

Pfizer Inc.
235 East 42nd Street
New York 10017
United States

Package leaflet: Information for the user

Trumenba
meningococcal group B vaccine
(recombinant, adsorbed)

Read all of this leaflet carefully before you or your child receives this vaccine because it contains important information for you or your child

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This vaccine has been prescribed for you or your child only.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Trumenba is and what it is used for

Trumenba is a vaccine to prevent invasive meningococcal disease, caused by *Neisseria meningitidis* serogroup B, for use in people 10 years and older. This is a type of bacteria that can cause serious and sometimes life-threatening infections such as meningitis (inflammation of the covering of the brain and spinal cord) and sepsis (blood poisoning).

The vaccine contains 2 important components from the surface of the bacteria.

The vaccine works by helping the body to make antibodies (the body's natural defences) which protect you or your child against this disease.

2. What you need to know before you or your child receives Trumenba

Trumenba should not be given
- if you or your child are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6 **What Trumenba contains**).
- if you or your child had severe allergic reaction (e.g., anaphylaxis) after any previous dose of Trumenba or to any component of this vaccine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before vaccination with Trumenba. Tell your doctor, pharmacist or nurse if you or your child:
- have a severe infection with a high fever. If this is the case, then vaccination will be postponed. The presence of a minor infection, such as a cold, should not require postponement of the vaccination, but talk to your doctor first.
- have a bleeding problem or bruise easily.
- receive treatment that prevent the blood from clotting.

- have a weakened immune system which may prevent you or your child from getting the full benefit from Trumenba.
- have had any problems after any dose of Trumenba such as a severe allergic reaction or problems with breathing.

Fainting, feeling faint, or other stress-related reactions can occur as a response to any needle injection. Tell your doctor, pharmacist or nurse if you have experienced this kind of reaction previously.

Other medicines and Trumenba
Tell your doctor, pharmacist or nurse if you or your child are using, have recently used or might use any other medicines or have recently received any other vaccine.

Trumenba can be given at the same time as any of the following vaccine components: tetanus, diphtheria, whooping cough (pertussis), poliovirus, papillomavirus, and meningococcal serogroups A, C, W, Y.

Administration of Trumenba with vaccines other than those mentioned above, has not been studied.

If you receive more than 1 vaccination at the same time it is important that different injection sites and syringes are used.

If you take medicines that affect your immune system (such as radiation therapy, corticosteroids, or some types of cancer chemotherapies), you may not get the full benefit of Trumenba.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before Trumenba is given. Your doctor may still recommend that you receive Trumenba if you are at risk of meningococcal disease.

Driving and using machines
Trumenba has no or little influence on the ability to drive and use machines.

However, some of the side effects mentioned under section 4 may temporarily affect you. If this occurs, wait until the effects wear off before driving or using machines.

Trumenba contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Trumenba is given

Trumenba will be given to you or your child by a doctor, pharmacist or nurse. It will be injected into the upper arm muscle.

It is important to follow the instructions from the doctor, pharmacist or nurse so that you or your child completes the course of injections.

Individuals 10 years and older
- Standard schedule: You or your child will receive 2 injections of the vaccine, the second injection is given 6 months after the first injection.
- Schedule for individuals at increased risk of invasive meningococcal disease: You or your child will receive 2 injections of the vaccine given at least 1 month apart and a third injection at least 4 months after the second injection.

- You or your child may be given a booster.

4. Possible side effects

Like all vaccines, this vaccine can cause side effects, although not everybody gets them.

When Trumenba is given to your or your child, the following side effects may occur:

Very common (may affect more than 1 in 10 people)
- Redness, swelling or pain at injection site
- Headache
- Diarrhea
- Nausea
- Muscle pain
- Joint pain
- Chills
- Fatigue

Common (may affect up to 1 in 10 people)
- Vomiting
- Fever ≥38°C

Not known (frequency cannot be estimated from the available data)
- Allergic reactions
- Fainting

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Trumenba

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C).

Syringes should be stored in the refrigerator horizontally to minimize the re-dispersion time.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trumenba contains
One dose (0.5 ml) contains:

Active substances:

MnB rLP2086 subfamily A	60 µg
MnB rLP2086 subfamily B	60 µg

Other ingredients:

Sodium chloride (see section 2 **Trumenba contains sodium**), histidine, water for injections, Aluminium Phosphate ($AlPO_4$) and polysorbate 80.

What Trumenba looks like and contents of the pack
Trumenba is a homogenous white suspension for injection, provided in a pre-filled syringe.

Pack sizes of 1 and 5 pre-filled syringes, with or without needles.

Not all pack sizes may be marketed.

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