Indication

TRUMENBA is indicated for active immunisation of individuals 10 years and older to prevent invasive meningococcal disease (IMD) caused by *Neisseria meningitidis* serogroup B.

Because they share

MenB, invasive meningococcal disease serogroup B.

Please see important safety information on page 7 and accompanying Prescribing Information on page 8.

You can order TRUMENBA by contacting Pfizer Vaccines on:

- ☎ 0800 089 4033
- 💼 VaccinesUK@pfizer.com

For more information, visit TRUMENBA.co.uk
**N. meningitidis** serogroup B infection is the UK’s leading cause of IMD\(^2,3\)

In the UK, MenB accounted for 57% of all reported cases of IMD in people 10–24 years old in 2015/16\(^2\)

IMD is unpredictable and can have devastating consequences\(^3\)–\(^6\)

- **Overall, 1 in 20 cases of IMD are fatal, typically within 24–48 hours**\(^3,5\)
- **15–24 year olds are around 2.5x more likely to die from MenB disease than infants are**\(^7\)
- **IMD survivors may have permanent, long-term sequelae such as:**\(^5,6\)
  - Mental and motor skill impairment
  - Skin scarring
  - Limb amputations
  - Neurological dysfunction
  - Vision or hearing impairment
  - Poorer quality of life

Up to 1 in 5 patients will suffer severe long-term consequences of IMD\(^3\)

---

*No cases of MenA, X or Z/E were reported in the epidemiological year 2015/2016.\(^2\)

*Other refers to invasive clinical meningococcal isolates that were non-groupable and ungrouped culture-negative but PCR screen (ctrA) positive and negative for the four genogroups (B, C, W and Y) cases.

Please click here for accompanying Prescribing Information.
Adolescents and young adults are at increased risk of MenB\textsuperscript{2,5,8}

A combination of increased meningococcal carriage and common social behaviours put adolescents and young adults at increased risk of infection.\textsuperscript{5,8,9}

\textbf{N. meningitidis} carriage is often asymptomatic but can lead to IMD\textsuperscript{3}

- Meningococcal bacteria carriage increases during late adolescence to a peak of approximately 24\% in 19-year-olds\textsuperscript{9}

- The typical behaviours and lifestyle of people in this age group are compatible with transmission of meningococcal bacteria\textsuperscript{5,8,9}

\textbf{TRUMENBA} is indicated for active immunisation of individuals 10 years and older to prevent invasive meningococcal disease caused by \textit{N. meningitidis} serogroup B\textsuperscript{1}

Please click here for accompanying Prescribing Information.
**TRUMENBA** is designed to help protect against diverse MenB strains in adolescents and young adults\(^1\)

**TRUMENBA** works by targeting both subfamilies of a protein critical to MenB survival\(^1\)

Over 96% of MenB strains in Europe express factor H binding protein (fHBP) variants from either subfamily \(\text{A}\) or \(\text{B}\), making fHBP an ideal target for a MenB vaccine\(^1\)

**TRUMENBA** is the only vaccine which targets both fHBP subfamilies \(\text{A}\) and \(\text{B}\) and which is designed to offer broad coverage against invasive MenB disease\(^{10}\)

Please click here for accompanying Prescribing Information.
**TRUMENBA** has demonstrated immunogenicity against MenB strains* in individuals 10 years and older.

The fHBP subfamily A and B variants expressed by the test strains were, by design, not identical to the fHBP variants included in the vaccine11

**European Phase 2 clinical trial†1,11**

**Two global Phase 3 clinical trials§¶**

78%–98%  
of patients achieved immune response against MenB test strains†  
Following 2 doses of TRUMENBA at 0 and 6 months

87%–99%  
of patients achieved immune response against MenB test strains†  
Following 3 doses of TRUMENBA at 0, 2, and 6 months†

The safety data in more than 15,000 individuals 10 years of age and older demonstrated that **TRUMENBA** has an acceptable safety profile†

The most common adverse reactions in clinical trials were†

- Headache
- Diarrhoea
- Nausea
- Muscle pain
- Joint pain
- Chills
- Fatigue
- Pain, redness, and swelling at the vaccination site

**TRUMENBA** elicits a broad and robust immune response following 2 or 3 doses and has an acceptable safety profile†

*Representative of MenB strains causing IMD.
†In a randomised, placebo-controlled, single-blinded, multicentre trial conducted in Europe, 1,713 adolescents 11 to 18 years of age were assigned randomly into 5 groups to receive 2 or 3 doses of TRUMENBA: 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).1,11
‡hSBA titre ≥1:8 (A56, B24, B44) or ≥1:16 (A22).1
§Randomised, active-controlled, observer-blinded, multicentre trial, 3,590 adolescents 10 to 18 years of age were randomised to receive TRUMENBA (0, 2 and 6 months) or hepatitis A vaccine (HAV)/saline.1
¶hSBA immune response: 87–99% against 4 primary MenB strains and 71–99% against 10 additional MenB strains. hSBA titre ≥1:8 for A07, A15, A29, A56, A63, B09, B15, B16, B24, and B44; ≥1:16 for A06, A12, A19, and A22.1

Please click here for accompanying Prescribing Information.
TRUMENBA offers two dosing schedules for adolescents and young adults

2-dose schedule

- 2 doses (0.5 ml each) administered 6 months apart

3-dose schedule

- 2 doses (0.5 ml each) administered at least 1 month apart, followed by a third dose at least 4 months after the second dose

Dosing considerations

- A booster dose should be considered following either dosing regimen for individuals at continued risk of IMD
- The use of this vaccine should be in accordance with official recommendations

TRUMENBA can be co-administered alongside:

- HPV4
- Tdap
- MenACWY
- TdaP-IPV

You can offer the protection of TRUMENBA to adolescents and young adults alongside other important vaccines

HPV4, quadrivalent human papillomavirus vaccine; Tdap, tetanus toxoid, reduced diphtheria toxoid, acellular pertussis vaccine adsorbed; MenACWY, meningococcal serogroups A, C, Y, W conjugate vaccine; Tdap-IPV, tetanus toxoid, reduced diphtheria toxoid, acellular pertussis, and inactivated poliovirus vaccine.

Please click here for accompanying Prescribing Information.
Administering **TRUMENBA**

- Before use, the pre-filled syringe should be shaken vigorously to ensure that a homogenous white suspension of TRUMENBA is obtained.
- TRUMENBA should be administered intramuscularly only. The preferred site for injection is the deltoid muscle of the upper arm.
- Do not mix TRUMENBA with any other vaccines or medicinal products in the same syringe.
- The TRUMENBA syringe tip cap and rubber plunger are not made with natural rubber latex.

How to store **TRUMENBA**

- Syringes should be stored **horizontally** in a refrigerator (2°C–8°C) to minimise re-dispersion time.
- TRUMENBA has a shelf-life of 3 years.
- Do not freeze.

Important safety information

- Hypersensitivity to the active substances or to any of the excipients.
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to TRUMENBA.
- As with any vaccine, vaccination with TRUMENBA may not protect all vaccine recipients.
- In clinical studies, the most common adverse reactions observed were injection site pain, redness and swelling at the vaccination site, headache, fatigue, chills, diarrhoea, muscle pain, joint pain, and nausea.
- Fertility, pregnancy and lactation: Vaccination during pregnancy/lactation may be considered when the possible advantages outweigh the potential risk.

**TRUMENBA** comes in a pre-filled syringe and has a shelf-life of 3 years.
References:

Prescribing Information:

This medicinal product is subject to additional monitoring. This will allow quick identification of any new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

TRUMENBA® suspension for injection in pre-filled syringe
Meningococcal group B vaccine (recombinant, adjuvanted). Please refer to the Summary of Product Characteristics (SmPC) before prescribing TRUMENBA®. Presentation: Each 0.5ml dose of Trumenba contains 60 μg of Neisseria meningitidis serogroup B fHbp subfamily A,1,2 and 60 μg of Neisseria meningitidis serogroup B fHbp subfamily A,2,3. Recombinant lipidated fHbp (factor H binding protein). 1 Produced in Escherichia coli cells by recombinant DNA technology. 2 Adsorbed on aluminium phosphate (0.25 milligram aluminium per dose).

Indications: Active immunisation of individuals 10 years and older to prevent invasive meningococcal disease caused by Neisseria meningitidis serogroup B. Dosage and Administration: For intramuscular injection only. Two-dose primary series: 2 doses administered at a 6 month interval. Three-dose primary series: Alternatively 2 doses administered 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. Contraindications: Hypersensitivity to the active substances or to any of the excipients. Special warnings and precautions for use: Do not inject intravenously, intradermally, or subcutaneously. Appropriate medical treatment should always be readily available in case of anaphylactic reactions following administration of the vaccine. Postpone vaccination in acute febrile illness. Trumenba should not be given to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, unless the potential benefit clearly outweighs the risk of administration. As with any vaccine, vaccination with Trumenba may not protect all vaccine recipients. There are no data on the use of Trumenba in immunocompromised individuals. Immuno-compromised individuals, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Trumenba. There are no data on the use of Trumenba in subjects above 65 years of age. Immune response: The immunogenicity of Trumenba following 2 or 3 vaccinations was evaluated in individuals 11 to 18 years of age (Study B1971012) and following 3 vaccinations in individuals 10 to 25 years of age (Studies B1971009 and B1971010). A response was defined as an hSBA titre of at least 1.8 or 1.16 depending on the hSBA strain. An hSBA titre of greater than or equal to 1.4 is assumed to be protective against meningococcal disease. A 4-fold increase in hSBA titre for each of the 4 primary meningococcal serogroup B test strains was defined as follows: (1) for subjects with a baseline hSBA titre < 1.4, a 4-fold response was defined as an hSBA titre ≥ 1.16. (2) For subjects with a baseline hSBA titre ≥ 1.4, a 4-fold response was defined as an hSBA titre ≥ 4 times the lower limit of quantification or ≥ 4 times the baseline titre, whichever was higher. A composite response was defined as a response for all 4 hSBA strains. In Study B1971012, 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). Of the 1,713 subjects randomised, 427 were in Group 1, 430 in Group 2, 427 were in Group 3, 286 were in Group 4, and 143 were in Group 5. All subjects received 4 study injections, either 2 or 3 doses of Trumenba and 1 or 2 doses of saline. The hSBA composite responses (for all 4 hSBA strains combined) observed after third dose for Groups 1, 2, and the second dose for Group 3 as the proportion of subjects achieving a response were: Group 1 83.1%, Group 2 82.7% and Group 3 73.5%. The proportion of subjects achieving a 4-fold increase in hSBA titre (%) to each of the 4 primary meningococcal serogroup B test strains was as follows: PMB80 (A22) Group 1 78.1%, Group 2 84.0% and Group 3 80.7%; PMB2001 (A56) Group 1 93.4%, Group 2 94.2% and Group 3 96.4%; PMB2948 (B24) Group 1 74.6%, Group 2 75.4.6% and Group 3 65.3%; PMB707 (B46) Group 1 82.2%, Group 2 81.7% and Group 3 66.8%. In Studies B1971009 and B1971016, the proportion of subjects achieving a defined hSBA titre 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, the additional hSBAs indicate and extend the breadth of vaccine coverage demonstrated by the 4 representative primary strains. Persistence of immunity and response to booster vaccination was investigated in Study B1971033, an open-label, follow-up study of subjects previously enrolled in a primary study, including Study B1971012. Subjects received a single booster dose of Trumenba approximately 4 years after receipt of a primary series of Trumenba. A booster response in hSBA responses at 1 month following the dose of Trumenba approximately 4 years after a primary series of 2 doses (Group 3) or 3 doses (Groups 1 and 2) was observed. The hSBA composite responses (for all 4 hSBA strains combined) after third dose for Groups 1, 2, and the second dose for Group 3 from Study B1971012 were: Group 1 55.7%, Group 2 18.2% and Group 3 36.4% 48 months after last primary dose and 1 month after booster dose were: Group 1 91.2%, Group 2 98.2% and Group 3 91.8%. Fertility, pregnancy and lactation: Vaccination during pregnancy/ lactation may be considered when the possible advantages outweigh the potential risk. Undesirable effects: See SmPC for full details. Very common (≥ 1/10) adverse events are headache, muscle pain (myalgia), joint pain (arthralgia), diarrhoea, nausea, chills, pain (arthralgia), diarrhoea, nausea, chills, fatigue, redness (erythema), swelling (induration) and pain at injection site. Common (≥ 1/100 to <1/10) adverse events are vomiting and pain (arthralgia), diarrhoea, nausea, chills, fatigue, redness (erythema), swelling (induration) and pain at injection site. Common (≥ 1/1000 to <1/100) adverse events are vomiting and fever ≥ 38 °C (Pyrexia). Allergic reactions have also been reported, frequency not known (cannot be estimated from available data). Legal Category: POM. Package Quantities: Pack of 1 single-dose pre-filled syringe (with separate needle). Cost: £75.00. Marketing Authorisation Number: EU/1/17/13187/001. Marketing Authorisation Holder: Pfizer Limited, Sandwich, Kent, CT13 9NU. United Kingdom. Further information is available on request from: Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK. Tel +44 (0)1304 616161. Adverse events should be reported. Reporting forms and information can be found at http://www.mhra.gov.uk/yellowcard Adverse events should also be reported to Pfizer Medical Information on 0804 616161.
Offer adolescents and young adults broad protection against MenB, in a 2-dose schedule¹

**TRUMENBA:**

- Targets both fHBP subfamilies, A and B¹
- Demonstrated immunogenicity in clinical trials against MenB strains expressing several different fHBP variants representative of MenB strains causing IMD¹,¹⁰
- Can be co-administered alongside¹
  - HPV4
  - MenACWY
  - Tdap
  - Tdap-IPV
- Included more than 15,000 individuals (10 years of age and older), in 11 clinical trials during its evaluation¹

You can order TRUMENBA by contacting Pfizer Vaccines on:

- ☎️ 0800 089 4033
- ✉️ VaccinesUK@pfizer.com

For more information, visit TRUMENBA.co.uk

⚠️ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions. Reporting forms and information can also be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to the Pfizer Medical Information department on 01304 616161

Please click here for accompanying Prescribing Information.
You can order TRUMENBA by contacting Pfizer Vaccines on:

- ☎ 0800 089 4033
- 🍀 VaccinesUK@pfizer.com

For more information, visit TRUMENBA.co.uk