PRESCRIBING INFORMATION

▼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.

TRUMENBA® suspension for injection in pre-filled syringe ▼
Meningococcal group B vaccine (recombinant, adsorbed)

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[1,2,3] and 60 µg of *Neisseria meningitidis* serogroup B fHbp subfamily B[1,2,3] .
[1] Recombinant lipidated fHbp (factor H binding protein); [2] Produced in *Escherichia coli* cells by recombinant DNA technology;[3] 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. There are no data available on the interchangeability of Trumenba with other meningococcal group B vaccines to complete the vaccination series. Safety and efficacy of Trumenba in children younger than 10 years of age have not been established. Currently available data for children 1 to 9 years of age are described in the SmPC; however, no recommendation on a posology can be made as data are limited.

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. Immunocompromised individuals, including individuals receiving immunosuppressant therapy, may have a diminished immune response to Trumenba. Individuals with familial complement deficiencies (for example, C5 or C3 deficiencies) and patients receiving treatments that inhibit 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. There are limited data on the use of Trumenba in individuals 40 to 65 years of age and there are no data on the use of Trumenba in individuals older than 65 years of age. 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.

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 B1971016). 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 quantitation or ≥ 4 times the baseline titre, whichever was higher. A composite response was defined as a response for all 4 hSBA strains combined. 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 were 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 81.7% 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 90.4%; PMB2948 (B24) Group 1 74.6%, Group 2 75.4% and Group 3 65.5%; PMB2707 (B44) 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 support 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 was observed as measured by hSBA 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). 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: Group1 19.6%, Group 2 30.2% and Group 3 9.8% 48 months after last primary dose and 26 months after booster dose were Group 2 48.1% and Group 3 44.4%. Group 1 subjects were not followed beyond 12 months post booster; last recorded response was 52.8%. *Immunogenicity in individuals 1 to 9 years of age:* The immunogenicity of Trumenba (0-, 2-, 6-month schedule) in toddlers and children 1 to 9 years of age was evaluated in 2 Phase 2 studies. At 1 month following series completion, 81.4% to 100% of subjects achieved a response to the 4 primary meningococcal test strains (defined as hSBA ≥ 1:16 for A22; ≥ 1:8 for A56, B24 and B44) compared to 0.4% to 6.5% at baseline. There are no persistence data in children 1 to < 2 years of age. In children 2 to 9 years of age, 6 months following series completion, 32.5%, 82.4%, 15.5% and 10.4% of participants maintained a response to the primary test strains A22, A56, B24 and B44, respectively.

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. In subjects 10 years of age and older, very common (≥ 1/10) adverse events are headache, muscle pain (myalgia); joint 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 fever ≥ 38 °C (pyrexia). Allergic reactions have also been reported, frequency not known (cannot be estimated from the available data). Adverse reactions following booster vaccination in 301 subjects 15 to 23 years of age were similar to adverse reactions during the primary Trumenba vaccination series approximately 4 years earlier. In a study of 220 toddlers 1 to < 2 years of age, the following adverse reactions occurred at a frequency of very common (≥ 1/10): drowsiness, irritability (fussiness), loss of or decreased appetite, fever, and injection site pain, swelling and redness. In a study of 294 children 2 to 9 years of age, the following adverse reactions occurred at a frequency of very common (≥ 1/10): headache, diarrhoea, vomiting, muscle pain, joint pain, fever, fatigue, and injection site pain, swelling and redness. In clinical studies, fever (≥ 38°C) occurred more frequently as subject age decreased.

Legal Category: POM. **Package Quantities:** Pack of 1 single-dose pre-filled syringe (with separate needle). **Cost: £75.00. Marketing Authorisation Number:** EU/1/17/1187/001. M**arketing Authorisation Holder:** Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. 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 www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Pfizer Medical Information on 01304 616161

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