TRUMENBA (Meningococcal Group B Vaccine) Frequently Asked Questions

What you need to know

Q. What is MenB disease?

A. MenB is an uncommon but potentially deadly bacterial infection that attacks the linings of the brain and spinal cord, called the meninges, and can also cause an infection of the blood.[1-3] *Neisseria meningitidis* is the bacterium that causes this disease, and MenB is one type of meningococcal disease.[1] MenB represents approximately 60% of all meningococcal disease cases among adolescents and young adults in the US.[4] All other common types of the disease (A, C, W, Y) comprise only about 40% of disease incidence in the US.

Early symptoms may seem like the flu, but MenB can lead to death within 24 hours.[1,2] This disease can also cause long-term effects in survivors, such as loss of limbs, seizures, or deafness.[5,6]

Q. What is TRUMENBA?

A. TRUMENBA is an FDA-approved vaccine for the prevention of MenB in individuals 10 through 25 years of age. Patients who participated in the TRUMENBA clinical trials were adolescents and young adults.[7] If your teen previously received a vaccine for meningococcal disease (such as the MCV4 vaccine), they may not be protected against MenB.[8]

Q. How should TRUMENBA be given?

A. TRUMENBA follows a 2- or 3-dose schedule.[7] Discuss with your teen's health care provider or pharmacist which schedule is appropriate for your teen.

- To help protect them against MenB, ensure your teen completes all recommended doses of TRUMENBA

Q. Who should be given TRUMENBA?

A. TRUMENBA is a vaccine indicated for individuals 10 through 25 years of age for active immunization to prevent invasive disease caused by *Neisseria meningitidis* group B.[7]

- 16 to 18 years is the preferred age recommended by the CDC for MenB vaccination[8]

CDC=Centers for Disease Control and Prevention.

Q. Who should not be given TRUMENBA?

A. TRUMENBA should not be given to anyone with a history of severe allergic reaction after a previous dose of TRUMENBA. Individuals with weakened immune systems may have a reduced immune response. TRUMENBA should only be given to pregnant women if it is clearly needed.[7]

Q. Are there any risks associated with TRUMENBA?

A. TRUMENBA, like any vaccine, could possibly cause serious problems, such as severe allergic reactions. The most common adverse reactions in adolescents and young adults were pain at injection site, fatigue, headache, and muscle pain.[7]

Q. What if there is a severe reaction? What should I look for?

A. Look for any unusual conditions, such as signs of a severe allergic reaction, a high fever, or changes in behavior. Signs of a severe allergic reaction may include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness.

Trumenba®
Meningococcal Group B Vaccine

Q. What should I do if there is a severe reaction?

A.

- Call 911 or a doctor, or get the person to a doctor right away
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given
- Ask your health care provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at **www.vaers.hhs.gov**, or by calling **1-800-822-7967.** *VAERS does not provide medical advice*

Q. How can I learn more?

A. Talk with your health care provider. Ask for the full Prescribing Information for TRUMENBA and suggestions for other sources of information. You can also

- Call your local or state health department
- Contact the Centers for Disease Control and Prevention (CDC) at **1-800-232-4636 (1-800-CDC-INFO)** or go to **www.cdc.gov/vaccines**
- Visit the American Academy of Pediatrics website at **https://www.aap.org**
- Visit the Immunization Action Coalition website at **http://www.immunize.org/vis/vis_meningococcal_b.asp**
- Call **1-844-TRUMENBA (878-6362),** 9 AM to 7 PM ET, Monday through Friday

INDICATION

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

IMPORTANT SAFETY INFORMATION

- Trumenba should not be given to anyone with a history of a severe allergic reaction after a previous dose of Trumenba
- Some individuals with weakened immune systems may have a reduced immune response
- Persons with certain complement deficiencies and persons receiving treatments such as Soliris® (eculizumab), are at increased risk for invasive disease caused by *N meningitidis* group B even with receipt of vaccination with Trumenba
- As with any vaccine, vaccination with Trumenba may not protect all vaccine recipients against *N meningitidis* group B infections
- Fainting can occur in association with administration of injectable vaccines, including Trumenba
- The most common adverse reactions in adolescents and young adults were pain at injection site, fatigue, headache, and muscle pain. Nausea was reported in adolescents in early phase studies
- Data are not available on the safety and effectiveness of using Trumenba and other meningococcal group B vaccines interchangeably to complete the vaccination series
- Tell your health care provider if you are pregnant, or plan to become pregnant
- Ask your health care provider about the risks and benefits of Trumenba. Only a health care provider can decide if Trumenba is right for you or your child

You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit www.vaers.hhs.gov or call 1-800-822-7967.

Call 1-844-TRUMENBA (878-6362), 9 AM to 7 PM ET, Monday through Friday, for more information.

Please click here for full Prescribing Information.

References: 1. Centers for Disease Control and Prevention. Meningococcal disease. Centers for Disease Control and Prevention website. http://www.cdc.gov/meningococcal/index.html. Updated April 9, 2018. Accessed August 21, 2018. **2.** Thompson MJ, Ninis N, Perera R, et al. Clinical recognition of meningococcal disease in children and adolescents. *Lancet.* 2006;367(9508):397-403. **3.** Soeters HM, McNamara LA, Whaley M, et al. Serogroup B meningococcal disease outbreak and carriage evaluation at a college—Rhode Island, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(22):606-607. **4.** Centers for Disease Control and Prevention. Enhanced Meningococcal Disease Surveillance Report, 2016. https://www.cdc.gov/meningococcal/downloads/NCIRD-EMS-Report.pdf. September 2017. Accessed August 21, 2018. **5.** Bettinger JA, Scheifele DW, Le Saux N, et al. The disease burden of invasive meningococcal serogroup B disease in Canada. *Pediatr Infect Dis J.* 2013;32(1):e20-e25. **6.** Borg J, Christie D, Coen PG, et al. Outcomes of meningococcal disease in adolescence: prospective, matched-cohort study. *Pediatrics.* 2009;123(3):e502-e509. **7.** TRUMENBA [package insert]. Philadelphia, PA: Pfizer Inc; 2018. **8.** MacNeil JR, Rubin L, Folaranmi T. Use of serogroup B meningococcal vaccines in adolescents and young adults: recommendations of the Advisory Committee on Immunization Practices, 2015. *MMWR Morb Mortal Wkly Rep.* 2015;64(41):1171-1176.

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