



# CDC Advisory Committee on Immunization Practices Votes to Recommend New Dosing Schedule for Vaccination with TRUMENBA® (Meningococcal Group B Vaccine)

Wednesday, October 19, 2016 - 02:02pm

Recommendation provides updated guidance for administering a two- or a three-dose series

**“Today’s ACIP recommendation is an important update that offers clear guidance to healthcare providers administering TRUMENBA to help prevent meningococcal group B disease, also known as MenB, in healthy adolescents and young adults, as well as those at increased risk for the disease”**

Pfizer Inc. (NYSE: PFE) announced today that the U.S. Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) voted to recommend that:

For persons at increased risk for meningococcal disease and for use during serogroup B outbreaks, 3 doses of TRUMENBA should be administered at 0, 1-2, and 6 months. When given to healthy adolescents who are not at increased risk for meningococcal disease, 2 doses of TRUMENBA should be administered at 0 and 6 months. If the second dose is given at an interval of less than 6 months, a third dose should be given at least 6 months after the first dose.

“Today’s ACIP recommendation is an important update that offers clear guidance to healthcare providers administering TRUMENBA to help prevent meningococcal group B disease, also known as MenB, in healthy adolescents and young adults, as well as those at increased risk for the disease,” said Dr. Laura York, Global Medical Lead for Meningococcal Vaccines, Pfizer Vaccines. “This new recommendation enables flexible vaccination dosing intervals depending on one’s risk of exposure to MenB, which makes it easier for healthcare providers to help protect individuals from this uncommon but life-threatening disease.”

The ACIP recommendation will be forwarded to the director of the CDC and the U.S. Department of Health and Human Services for review and approval. Once approved, the recommendations are published in the Morbidity and Mortality Weekly Report (MMWR). The Affordable Care Act (ACA) and Vaccines for Children (VFC) program ensure coverage for all vaccines administered in accordance with ACIP recommendations. Healthcare providers should contact their individual plan to determine specific coverage and reimbursement requirements.

In 2015, the CDC’s ACIP recommended serogroup B meningococcal vaccination for certain persons aged 10 years and older at increased risk for meningococcal disease.<sup>1</sup> They also recommended that a MenB vaccine series may be administered to adolescents and young adults 16 through 23 years of age (preferred age 16 through 18) to provide short-term protection against most strains of MenB disease.<sup>2</sup> In October 2014, TRUMENBA was granted Accelerated Approval by the U.S. Food and Drug Administration (FDA) for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age.

#### U.S. Indication for TRUMENBA® (Meningococcal Group B Vaccine)

TRUMENBA® (Meningococcal Group B Vaccine) is indicated for active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age.

Approval of TRUMENBA is based on the demonstration of immune response, as measured by serum bactericidal activity against four serogroup B strains representative of prevalent strains in the United States and Europe. The effectiveness of TRUMENBA against diverse serogroup B strains has not been confirmed.

#### Important Safety Information

TRUMENBA® (Meningococcal Group B Vaccine) should not be given to anyone with a history of a severe allergic reaction after a previous dose of TRUMENBA.

Individuals with weakened immune systems may have a reduced immune response.

The most common adverse reactions were pain at the injection site, fatigue, headache, muscle pain, and chills.

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 healthcare provider if you are pregnant, or plan to become pregnant.

Ask your healthcare provider about the risks and benefits of TRUMENBA. Only a healthcare provider can decide if TRUMENBA is right for you or your child.

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

For the full prescribing information for TRUMENBA, please visit [www.trumenba.com](http://www.trumenba.com).

#### About TRUMENBA® (Meningococcal Group B Vaccine)

TRUMENBA® (Meningococcal Group B Vaccine) 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). 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. 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.<sup>3</sup>

As with any vaccine, TRUMENBA may not prevent disease in all vaccinated individuals. The frequency of meningococcal disease caused by serogroup B varies geographically, and could influence the ability to evaluate effectiveness of the vaccine in any given country. Based on the low incidence of meningococcal disease, placebo-controlled clinical trials for TRUMENBA were considered unfeasible due to the size of the study that would be required and were not performed. Licensure of TRUMENBA was based on

demonstration of immune responses measured using a serum bactericidal assay with human complement (hSBA).

In 2014, TRUMENBA was reviewed and received accelerated approval under the FDA's Breakthrough Therapy designation and Priority Review programs.

In April 2016, the FDA approved a revised dosing schedule for TRUMENBA based on data from the U.S. and European Phase 2 trials.

TRUMENBA is now approved to be administered in two dosing schedules:

Three-Dose Schedule: Administer a dose (0.5 mL) at 0, 1-2, and 6 months; or Two-Dose Schedule: Administer a dose (0.5 mL) at 0 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.<sup>3</sup>

#### About Group B Meningococcal (MenB) Disease

The majority of invasive meningococcal disease cases worldwide can be attributed to five *Neisseria meningitidis* serogroups (A, B, C, W and Y).<sup>4</sup> MenB affects all age groups in the U.S., but incidence is highest among infants younger than one year, adolescents and young adults.<sup>5</sup> MenB accounts for nearly 50 percent of all U.S. meningococcal cases in 17-23 year olds.<sup>6</sup>

Although uncommon, MenB may result in life-altering, significant long-term and permanent medical disabilities.<sup>7,8,9</sup> However, even with antibiotic treatment, 10 to 15 percent of patients with MenB die and many of those who survive are afflicted with long-term disabilities, such as brain damage, hearing loss, learning disabilities or limb amputations.<sup>10,11,12</sup>

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as

one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at [www.pfizer.com](http://www.pfizer.com). In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer\_News, LinkedIn, YouTube, and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

DISCLOSURE NOTICE: The information contained in this release is as of October 19, 2016. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about TRUMENBA® (Meningococcal Group B Vaccine), including its potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial impact of the ACIP's recommendations regarding TRUMENBA; uncertainties regarding the commercial success of TRUMENBA; the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results; whether and when any biologics license applications may be filed in any additional jurisdictions for TRUMENBA; whether and when any applications that are pending or that may be filed may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the immunogenicity and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of TRUMENBA; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

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- 3 TRUMENBA (Meningococcal Group B Vaccine) Prescribing Information. Philadelphia, PA: Pfizer, Inc. 2016.
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- 11 Centers for Disease Control and Prevention. Meningococcal Vaccines for Preteens, Teens. Last updated April 18, 2016. Accessed June 1, 2016.
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