

Bexsero®: Targeting Meningococcal Group B

- *Bexsero® (Meningococcal Group B Vaccine) is approved in the US for active immunization to help prevent invasive meningococcal disease caused by *Neisseria meningitidis* group B in adolescents and young adults from 10 years through 25 years of age¹*
- *Bexsero is administered in a two-dose series at least one month apart, which may allow patients to complete the series in a summer^{1,2}*
- *Bexsero is now licensed in 37 countries; since first approval in Europe, over 1 million doses shipped worldwide²*
- *Phase III clinical data in adolescents showed Bexsero generated a protective immune response after two doses²*

About Bexsero

In January 2015, Bexsero® was approved by the US Food & Drug Administration (FDA) for active immunization to help prevent invasive meningococcal disease caused by *Neisseria meningitidis* group B in adolescents and young adults from 10 years through 25 years of age¹. The effectiveness of Bexsero against diverse group B strains has not been confirmed.

Outside of the US, Bexsero is currently licensed in 36 countries including the European Union, Australia and Canada for use in individuals from 2 months of age and older².

Clinical data and experience in other countries where the vaccine is approved reinforce the positive attributes of Bexsero

- In two Phase III studies, **Bexsero demonstrated a protective immune response in adolescents and young adults after two doses** (doses administered at least one month apart)²
- The US approval of Bexsero was based on safety studies using 3,058 patients¹

In response to outbreaks of meningococcal group B disease at Princeton University and the University of California-Santa Barbara (UCSB), Bexsero was administered as a two-dose series at least one month apart, as part of a clinical trial initiated by US Centers for Disease Control and Prevention (CDC) under an Investigational New Drug (IND) application. Information on serious adverse events was collected for a period of 30 days after each dose from 15,351 individuals who received at least one dose. Overall, 50 individuals (0.3%) reported serious adverse events, which is consistent with results observed in previous studies¹.

Bexsero – Meningococcal Group B Vaccine

Bexsero is the result of more than 20 years of pioneering research in vaccine development. Bexsero was developed using an award-winning scientific approach that involved decoding the genetic makeup (genome sequence) of *Neisseria meningitidis* group B². This innovative approach provides the foundation for a new generation of vaccines that can help prevent other diseases with a significant diversity of disease-causing strains².

Novartis is committed to providing successful vaccines to help globally protect against the five main groups of meningococcal bacteria (A, B, C, W-135 and Y)³. The US approval of Bexsero underscores the unique leadership position of Novartis in the global fight against this devastating disease¹. Bexsero and Menveo® (Meningococcal Group A, C, W-135 and Y conjugate vaccine) help to protect against the five main groups of meningococcal bacteria that cause

Bexsero is the only meningococcal group B vaccine approved in the US with a two-dose regimen^{1,2}

Clinical data show Bexsero helps protect against meningococcal group B disease²

Bexsero uses groundbreaking technology to help protect against meningococcal group B disease²

the majority of cases across the globe^{3,4}. In the US, the most prevalent groups are B, C and Y³.

Meningococcal Group B – A cause of devastating disease

Invasive meningococcal disease, which may present as bacterial meningitis and while rare, can have serious consequences including lifelong disability and sometimes death within 24 hours of symptom onset^{3,5,6,7}. *Neisseria meningitidis* group B has become one of the most prevalent groups that cause meningococcal disease in the US, accounting for 33 percent of all reported cases in 2013⁸. Even with appropriate treatment, as many as 10 percent of people with meningococcal disease will die and almost one in five survivors will suffer long-term disability^{7,9,10}. Adolescents and young adults are at risk of contracting meningococcal disease due to social factors, such as kissing and living in college dormitories^{3,11}.

Neisseria meningitidis group B has become the most prevalent group in the US, accounting for 33% of all cases in 2013⁸

References

1. Bexsero Prescribing Information.
2. Novartis data on file.
3. Centers for Disease Control and Prevention (CDC). Prevention and control of meningococcal disease – recommendations of the Advisory Committee on Immunization practices (ACIP). Morbidity and Mortality Weekly Report (MMWR). 2013; 62(2):1-13. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>. Accessed January 2015.
4. Menveo Prescribing Information.
5. Thompson MJ, Ninis N, Perera R, et al. Clinical recognition of meningococcal disease in children and adolescents. *Lancet* 2006;367(9508):397-403.
6. de Greeff SC, de Melker HE, Schouls LM, Spanjaard L, van Deuren M. Pre-admission clinical course of meningococcal disease and opportunities for the earlier start of appropriate intervention: a prospective epidemiological study on 752 patients in the Netherlands, 2003–2005. *Eur J Clin Microbiol Infect Dis* 2008;27:985-992.
7. Cohn AC, MacNeil JR, Harrison LH, et al. Changes in *Neisseria meningitidis* disease epidemiology in the United States, 1998–2007: implications for prevention of meningococcal disease. *Clin Infect Dis* 2010;50:184–91.
8. Centers for Disease Control and Prevention (CDC). Active Bacterial Core Surveillance (ABCs) Report Emerging Infections Program Network – *Neisseria meningitidis*, 2013-provisional. <http://www.cdc.gov/abcs/reports-findings/survreports/менинг13.pdf>. Accessed January 2015.
9. Kirsch EA, Barton RP, Kitchen L, Giroir BP. Pathophysiology, treatment and outcome of meningococemia: a review and recent experience. *Pediatr Infect Dis J* 1996;15:967-79.
10. Edwards MS, Baker CJ. Complications and sequelae of meningococcal infections in children. *J Pediatr* 1981;99:540-5.
11. World Health Organization (WHO). Meningococcal meningitis: fact sheet #141. November 2012. Available at: <http://www.who.int/mediacentre/factsheets/fs141/en>. Accessed January 2015.