

New Combination Vaccine to Protect Children against Two Deadly Bacteria

As of June 14, 2012, the U.S Food and Drug Agency has approved a new vaccine made by GlaxoSmithKline PLC named Menhibrix which can prevent potentially deadly infections caused by the bacteria *Neisseria meningitidis* serogroups C and Y and *Haemophilus influenzae* type b. The four-dose series follows the same administration schedule typically seen in the other childhood vaccinations with doses given at 2, 4, 6 and 12 through 15 months of age. The first dose may be given as early as 6 weeks of age, while the fourth dose may be given as late as 18 months of age. This is the first vaccine offering immunity of this type that can be given to infants at such an early age. Also, this drug gives health care providers the option of combining Hib immunization with meningococcal C and Y immunization without increasing the number of shots needed for infants and toddlers.

Neisseria meningitidis is known to cause meningococcal disease while *Haemophilus influenzae* causes Hib disease, both of which can be life threatening. These bacteria can infiltrate the blood stream and lead to sepsis. From there it can go to the cerebral spinal fluid and cause meningitis. Meningococcal and Hib diseases are particularly dangerous because both follow a rapid progression and can result in serious, life-altering health consequences such as blindness, mental retardation, amputations, or even death. Without vaccination, children younger than 2 years are at particularly increased risk for developing these infections. Both diseases present with early, non-specific side effects such as fever, vomiting, and neck pain or stiffness. This can make these serious diseases difficult to distinguish from other common childhood illnesses like the flu, which delays diagnosis and treatment.

Trials were performed examining the immune responses of several hundred U.S. infants and toddlers vaccinated with the drug in order to determine its effectiveness. According to the FDA, the immunity seen for the Hib component was similar to that found in infants and toddlers who received an FDA-approved vaccine active in preventing invasive Hib disease. Additionally, the FDA also states that similar results were exhibited for the meningococcal component of the drug. The vaccine was shown to produce antibodies in the blood at protective levels against invasive meningococcal disease caused by serogroups C and Y.

The safety profile of Menhibrix was evaluated in clinical trials involving 7,521 infants and toddlers receiving at least one dose of the drug over seven years throughout the United States, Mexico, Australia, Belgium and Germany. Of these participants, 3,349 were located in the USA. The most common adverse events seen in these clinical trials included pain and redness at the injection site, irritability, drowsiness and loss of appetite.

References

- Press Announcements: **FDA approves new combination vaccine that protects children against two bacterial diseases. FDA.** Available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm308350.htm>
- Menhibrix Approved to Prevent Bacterial Infections in Youngsters. Yahoo News. Available at <http://news.yahoo.com/menhibrix-approved-prevent-bacterial-infections-youngsters-160405583.html>

- FDA Approves GlaxoSmithKline's New Combo Vaccine Menhibrix. The PharmaLetter. Available at <http://www.thepharmaletter.com/file/114199/fda-approves-glaxosmithklines-new-combo-vaccine-menhibrix.html>

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