

**Menactra® (Meningococcal [Groups A, C, Y and W-135] Polysaccharide
Diphtheria Toxoid Conjugate Vaccine)**
Q&A – Frequently Asked Questions

I. GENERAL PRODUCT QUESTIONS

Q1. What is Menactra vaccine?

A1. Menactra vaccine is the first quadrivalent conjugate vaccine licensed in the U.S. for the prevention of meningococcal disease. Menactra vaccine offers protection against four of the most common serogroups of the bacterium that cause meningococcal infection, *Neisseria meningitidis* serogroups A, C, Y, and W-135. No vaccine is available in the U.S. for protection against infection from serogroup B.¹

Q2. When was Menactra vaccine first licensed in the U.S.?

A2. Menactra vaccine was first licensed by the Food and Drug Administration (FDA) for use in adolescents and adults 11 years to 55 years of age in January 2005. In October 2007, the FDA granted licensure of Menactra vaccine for use in children 2 years through 10 years of age.²

Q3. What is the age indication for Menactra vaccine?

A3. Menactra vaccine is indicated for active immunization of individuals 2 through 55 years of age for protection against invasive meningococcal disease caused by *N meningitidis* serogroups A, C, Y, and W-135.³

Q4. Are there other meningococcal vaccines available?

A4. Sanofi Pasteur is currently the only manufacturer of meningococcal vaccine in the U.S. The company offers two products: Menactra vaccine, which is a conjugate vaccine and Menomune®-A/C/Y/W-135 (Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined), which is a polysaccharide vaccine.⁴

Q5. How does Menactra vaccine compare to Menomune–A/C/Y/W-135 vaccine?

A5. Both Menactra vaccine and Menomune-A/C/Y/W-135 vaccine contain polysaccharide antigens from meningococcal bacteria serogroups A, C, Y, and W-135. Menomune–A/C/Y/W-135 vaccine is a polysaccharide vaccine. It is immunogenic, but protection lasts only 3 to 5 years. Menactra vaccine is a “conjugated” polysaccharide vaccine, meaning that it has a protein carrier bound to the polysaccharide. Successful conjugate vaccine protection has the potential to last many years and respond well to booster doses.¹

Q6. After inoculation with Menactra vaccine, how long until protective antibody levels are reached?

A6. Following immunization with Menactra vaccine, protective antibody levels are usually achieved within 7 to 10 days.¹

Q7. How is Menactra vaccine administered?

A7. Menactra vaccine is administered in a single dose via intramuscular injection.³

Q8. What are the adverse reactions to Menactra vaccine?

A8. In clinical trials, Menactra vaccine was shown to be safe. Adverse reactions are generally mild and consist mainly of injection site pain, redness, swelling and induration for individuals 2 through 55 years of age. Systemic reactions such as headache and fatigue were reported as mild and generally resolved within 3 days of vaccination.³

Menactra vaccine is contraindicated in persons with known hypersensitivity to any component of the vaccine or to latex, which is used in the vial stopper. Nor should it be given to a person who has a history of Guillain-Barré syndrome.³

Q9. Does Menactra vaccine contain thimerosal as a preservative?

A9. The vaccine does not contain thimerosal or any other preservative.³

Q10. How many cases of meningococcal disease are vaccine-preventable?

A10. Menactra vaccine and the older polysaccharide vaccine, Menomune–A/C/Y/W-135 vaccine, offer protection against four of the most common serogroups of the bacterium that cause meningococcal disease – *N meningitidis* serogroups A, C, Y, and W-135.¹ In the U.S., serogroups A, C, Y, and W-135 account for the majority of cases among adolescents and young adults,⁵ 48 percent of cases in children 2 years through 5 years of age, and 65 percent of cases among children 6 years through 11 years of age.⁶ Currently, there is no licensed vaccine in the U.S. that offers protection against serogroup B.¹

Q11. Where is Menactra vaccine manufactured?

A11. Swiftwater, Pennsylvania – in the Pocono Mountains of Northeast PA.³

Q12. Is there a new manufacturing plant being built? When will the new manufacturing facility be complete and how much will this increase capacity?

A12. A new manufacturing plant is being built in Swiftwater, PA and Menactra vaccine capacity is expected to sufficiently meet all current product demand forecasts.

Q13. Is Menactra vaccine covered by insurance for all groups recommended for vaccination?

A13. The majority of insurers cover the cost of the meningococcal vaccine for those groups recommended for vaccination by the Centers for Disease Control and Prevention (CDC). Individuals should check the policies offered by their employer to determine whether vaccinations are covered under their insurance plan.

Q14. Is Menactra vaccine available through the Vaccines for Children (VFC) program?

A14. Yes. Menactra vaccine is available to eligible children and adolescents meeting at least one of four criteria established by the CDC. For more information about the VFC program and criteria requirements, please visit: <http://www.cdc.gov/nip/vfc/default.htm>.⁷

II. POLICY QUESTION

Q1. What are the CDC recommendations for meningococcal vaccination?

- A1. The CDC recommends meningococcal immunization for all adolescents 11 years through 18 years of age. Additional groups recommended for the vaccine include:
- College freshmen living in dormitories
 - Children 2 years through 10 years of age at increased risk for contracting the disease
 - Microbiologists routinely exposed to isolates of *N meningitidis*
 - Military recruits
 - Travelers to or residents of countries in which *N meningitidis* is hyperendemic or epidemic
 - Those with terminal complement component deficiencies
 - Persons with anatomic or functional asplenia
 - Persons who wish to decrease their risk for meningococcal disease^{2,8}

III. DISEASE QUESTIONS

Q1. What is meningococcal disease?

- A1. Meningococcal disease is a rare, but potentially fatal bacterial infection that strikes between 1,000 and 2,600 Americans each year,⁹ causing meningitis (severe swelling of the brain and spinal cord) or meningococemia (sepsis) in the majority of cases.¹⁰

Approximately 10 percent of individuals who contract meningococcal disease will die. Of those who survive, up to 1 in 5 suffer permanent disabilities such as hearing loss, neurological damage, and limb amputations.¹ Meningococcal disease often begins with symptoms that can be mistaken for the flu or other common viral illnesses. Unlike common viral illnesses, meningococcal disease can progress very rapidly and kill an otherwise healthy person within 24 hours.¹¹⁻¹³

Q2. What are the symptoms of meningococcal disease?

- A2. Early symptoms of meningococcal disease often resemble symptoms of the flu and other common viral illness, and may include high fever, severe headache, stiff neck, confusion, vomiting, exhaustion and/or a rash.¹⁵ Unlike common viral illnesses, meningococcal disease can progress very rapidly and kill an otherwise healthy person within 24 hours.¹¹⁻¹³

Q3. How is meningococcal disease transmitted?

- A3. Meningococcal disease is spread through the exchange of fluids found in the nose (such as nose mucus) and throat (such as saliva and “spit”), usually through close contact with someone who carries the bacteria or is ill with meningococcal infection.^{14,15}

Q4. How many cases of meningococcal disease occur in the U.S.?

- A4. Meningococcal disease affects between 1,000 and 2,600 people in the U.S. each year.⁹

Q5. Who is at risk for contracting meningococcal disease?

- A5. Young children and adolescents are at highest risk for contracting meningococcal disease. While rates are highest among infants and young children under 1 year of age, rates begin to rise in early adolescence and peak between 15 years and 24 years of age.⁵

Q6. Why is meningococcal disease dangerous?

A6. Meningococcal disease is very dangerous because it can begin with mild symptoms that resemble the flu and other viral illnesses, but can get worse very quickly.¹⁴ Although rare, meningococcal disease can kill an otherwise healthy young person within 24 hours.¹¹⁻¹³

In fact, death rates from meningococcal disease are up to five times higher among adolescents and young adults (15 to 24 years of age) compared with the general population.⁵ Of those who survive, 1 in 5 will suffer from permanent disabilities, including amputation of limbs, fingers, or toes, severe scarring, brain damage, hearing loss, organ damage and/or emotional and psychological problems.¹

Q7. Can meningococcal disease be treated?

A7. Yes. Meningococcal disease can be treated with intravenous antibiotics; however, antibiotic treatment does not always guarantee a full recovery.¹⁵

Q8. What is the difference between bacterial and viral meningitis?

A8. Bacterial meningitis is a serious, potentially fatal bacterial infection of the tissues surrounding the brain and spinal cord. The most common types of bacterial meningitis can be potentially prevented through vaccination.⁵

Viral meningitis is serious, but usually not life-threatening and caused by one of several types of viruses. The most common types of viral meningitis cannot be prevented through vaccination.¹⁶

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