

**Product:** Meningococcal group A, C, W and Y conjugate vaccine (MenQuadfi)

**Strength:** 0.5 mL Solution for Intramuscular Injection

**Presentation:** Type 1 Clear Glass Vial in Packs of 1 or 5 single dose (0.5 mL)

**I:** *Meningococcal group A, C, W and Y conjugate vaccine* - For the active immunization of individuals from the age of 12 months and older against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y.

**C:** Hypersensitivity to the active substances or to any of the excipients listed or after previous administration of the vaccine or a vaccine containing the same components.

**W/P:** Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following administration of the vaccine. Vaccination should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, should not result in the deferral of vaccination. Syncope (fainting) and other anxiety-related reactions can occur following or even before any vaccination as a psychogenic response to the needle injection thus procedures should be in place to prevent injury. Should be given with caution to individuals with any coagulation disorder, and weak immune system. It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate immune response may not be elicited. For pregnant, or breast-feeding, consult your healthcare provider before receiving the vaccine.

**Interactions:** Injection sites on separate limbs, preferably contralateral, and separate syringes must be used in the case of concomitant administration. It may be expected that in patients receiving immunosuppressive treatment an adequate immune response may not be elicited.

**AE:** Tenderness, redness, or swelling where the injection was given, feeling irritable, muscle pain, loss of appetite, feeling drowsy, headache, fever

**PK/ PD:** MenQuadfi works by stimulating the vaccinated person natural defense, to produce protective antibodies against the bacteria. It induces the production of bactericidal antibodies specific to the capsular polysaccharides of *Neisseria meningitidis* serogroups A, C, W, and Y. It does not protect against infections caused by other types of *Neisseria meningitidis*, meningitis, or septicemia caused by other bacteria or viruses. The immunogenicity of a single dose of MenQuadfi for primary vaccination in toddlers (12-23 months of age), children and adolescents (2-17 years of age), adults (18-55 years of age) and older adults (56 years and above) was assessed in six pivotal studies. The immunogenicity of a single dose of MenQuadfi for booster vaccination (subjects 15-55 years of age) was assessed in one pivotal study. Primary immunogenicity analyses were conducted by measuring serum bactericidal activity (SBA) using human serum as the source of exogenous complement (hSBA). Rabbit complement (rSBA) data are available in subsets in all age groups and generally follows the trends observed with human complement (hSBA) data. Clinical data are not yet available on the persistence of antibody responses following primary vaccination with MenQuadfi nor for booster vaccination in individuals primed with MenQuadfi. Non-clinical safety data revealed no special risks for humans based on a developmental and reproductive toxicity study in female rabbits.

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Sanofi Pasteur Inc.

21st & 22nd Floors, One World Place Corporate Offices  
32nd Street, Bonifacio Global City, Taguig City, Metro Manila  
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