MenQuadfi® [Meningococcal (Groups A, C, Y, W) Conjugate Vaccine]

MenQuadfi is a vaccine indicated for active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y. MenQuadfi is approved for use in individuals 2 years of age and older. MenQuadfi does not prevent *N meningitidis* serogroup B disease.

IMPORTANT SAFETY INFORMATION

MenQuadfi should not be administered to anyone who has had a severe allergic reaction to any component of the vaccine, or after a previous dose of MenQuadfi or any other tetanus toxoid-containing vaccine.

Appropriate observation and medical treatment should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to MenQuadfi. Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (eg, eculizumab) are at increased risk for invasive disease caused by *N meningitidis*, including invasive disease caused by serogroups A, C, W, and Y, even if they develop antibodies following vaccination with MenQuadfi.

Syncope can occur following, or even before, vaccination with MenQuadfi. Procedures should be in place to prevent falling and injury and to manage syncope.

Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of another US-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision to give MenQuadfi to persons with a history of GBS should take into account the expected benefits and potential risks.

Immunization with MenQuadfi does not substitute for routine tetanus immunization.

Vaccination with MenQuadfi may not protect all vaccine recipients.

The most common adverse reactions following a primary dose of MenQuadfi in individuals 2 years of age and older include pain at the injection site; myalgia, headache, and malaise. Other common adverse reactions in children 2 through 9 years of age include erythema and swelling at the injection site. In adolescents and adults, rates of solicited adverse reactions following a booster dose were comparable to those observed following primary vaccination. Other adverse reactions may occur.

Please see full Prescribing Information for MenQuadfi