Prescribing Information: MenQuadfi ▼ solution for injection, Meningococcal Group A, C, W and Y conjugate vaccine

Please refer to Summary of Product Characteristics for full product information before prescribing

Presentation: One dose (0.5 mL) contains 10 micrograms of *Neisseria meningitidis* group A, C, Y and W polysaccharide each. It contains 55 micrograms of conjugated to tetanus toxoid carrier protein.

Indication: MenQuadfi is indicated for active immunisation of individuals from the age of 12 months and older against invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y. The use of this vaccine should be in accordance with available official recommendations.

Dosage and Administration: For Primary vaccination of individuals 12 months and older, one single dose of 0.5ml should be given. For Booster vaccination, a single 0.5 mL dose of MenQuadfi may be used to boost subjects who have previously received a meningococcal vaccine containing the same serogroups. Long-term antibody persistence data following vaccination with MenQuadfi are available up to 7 years after vaccination. There are no data available to indicate the need for or timing of a booster dose of MenQuadfi. The safety and immunogenicity of MenQuadfi in individuals under 12 months of age have not yet been established. For intramuscular injection only, preferably in the deltoid region or anterolateral thigh depending on the recipient's age and muscle mass. The vaccine should be inspected visually for any particulate matter and/or variation of physical aspect (or discolouration) prior to administration.

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

Precautions and Warnings:

Hypersensitivity: As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following administration of the vaccine.

Intercurrent illness: Vaccination should be postponed in individuals suffering from an acute severe febrile illness.

Syncope: Syncope (fainting) and other anxiety-related reactions can occur following or even before any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent falling or injury and to manage syncope.

Thrombocytopenia and coagulation disorders:

MenQuadfi should be given with caution to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, unless the potential benefit clearly outweighs the risk of administration. *Protection:* MenQuadfi will only protect against *Neisseria meningitidis* groups A, C, W, and Y. The vaccine will not protect against any other *Neisseria meningitidis* groups. As with any vaccine, vaccination with MenQuadfi may not protect all vaccine recipients. Waning of serum bactericidal antibody titres against serogroup A when using human complement in the assay (hSBA) has been reported for MenQuadfi and other quadrivalent meningococcal vaccines. The clinical relevance of this observation is unknown. However, if an individual is expected to be at particular risk of exposure to serogroup A and received a dose of MenQuadfi more than approximately one year previously, consideration may be given to administering a booster dose.

Toddlers who previously received serogroup C meningococcal conjugate vaccine during infancy had a lower hSBA mean titre against serotype A after receiving a single dose of MenQuadfi. *Immunodeficiency:* It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate immune response may not be elicited. No data on immunocompromised patients are available.

Tetanus immunisation: Immunisation with MenQuadfi vaccine does not substitute for routine tetanus immunisation. Co-administration of MenQuadfi with a tetanus toxoid-containing vaccine does not impair the response to tetanus toxoid or impact the safety.

Sodium content: This medicine contains less than 1 mmol sodium (23 mg) per dose essentially, 'sodium-free'.

Interactions: Injection sites on separate limbs and separate syringes must be used in the case of concomitant administration with other vaccines. For ages 12-23 months, MenQuadfi can be co-administered with the measles-mumps-rubella vaccine (MMR) and varicella vaccine (V), combined diphtheria - tetanus - acellular pertussis (DTaP) vaccines, including combination DTaP vaccines with hepatitis B (HBV), inactivated poliovirus (IPV) or Haemophilus influenzae type b (Hib) such as DTaP-IPV-HB-Hib (Hib conjugated to tetanus toxoid) vaccine and 13-valent pneumococcal polysaccharide conjugated vaccine (PCV-13). For ages 10-17 years, MenQuadfi can be co-administered with diphtheria, tetanus, pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) (Tdap) and human papillomavirus vaccine (recombinant, adsorbed) (HPV). There was no impact on the immune response to MenQuadfi when a meningococcal serogroup B vaccine was co-administered. As a precaution in children 12-23 months of age at high risk for serogroup A disease, consideration might be given for administration of MenQuadfi and PCV-13 vaccines separately. Meningococcal vaccine naïve children aged 10-17 years had non inferior response for PT and lower antibody responses to FHA, PRN and FIM when Tdap vaccine was administered concomitantly with MenQuadfi and HPV compared to co-administration with HPV vaccine alone.

Fertility, pregnancy and lactation: *Pregnancy:* MenQuadfi should be used during pregnancy only if the expected benefits for the mother outweigh the potential risks, including those for the foetus. *Breast-feeding:* It is unknown whether MenQuadfi is excreted in human milk. MenQuadfi should only be used during breast-feeding when the possible advantages outweigh the potential risks.

Adverse Reactions: Very common (≥1/10): *12 months through 23 months* (appetite lost, irritability, drowsiness, abnormal crying, at the injection site: tenderness/pain, erythema, swelling); *2 years of age and above* (headache, myalgia, malaise, injection site pain).

Common (≥1/100 to <1/10): *12 months through 23 months* (vomiting, diarrhoea, fever); *2 years of age and above* (fever, at the injection site: swelling, erythema). Other Serious Adverse Drug Reactions:

Very Rare (<1/10,000): Anaphylaxis. Not known: Hypersensitivity. *Older population:* Overall, within 7 days after vaccination with a single dose of MenQuadfi, the same injection site and systemic adverse reactions were observed in older (≥56 years of age) and younger adults (18 through 55 years old) but at lower frequencies; except for injection site pruritus, which was more frequent

(common) in older adults. These adverse reactions mostly were mild or moderate in intensity.
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Legal Category: POM
Marketing Authorisation Number: PLGB 04425/0878

Marketing Authorisation Holder: Aventis Pharma Ltd, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK (trading as Sanofi Pasteur)
Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK Or uk-medicalinformation@sanofi.com
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com