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

Please refer to Summary of Product Characteristics (SmPC) for full product information before prescribing.

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

Indication: 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 0.5 mL 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. MenQuadfi should not be administered subcutaneously, intravascularly or intradermally.

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.

Warnings and Precautions: It is good clinical practice to precede vaccination by a review of the medical history (especially regarding previous vaccination and possible occurrence of undesirable effects) and a clinical examination. 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. Lower hSBA geometric mean titres (GMTs) against serogroup A have been observed after a single dose of MenQuadfi was administered to toddlers who previously received serogroup C meningococcal conjugate vaccine (MenC-CRM) during infancy. Nevertheless, seroprotection rates were comparable between treatment groups. The clinical relevance of this observation is unknown. This aspect might be considered for individuals at high risk for MenA infection who received MenC-CRM vaccine in their first year of life. Immunodeficiency: It may be expected that in patients receiving immunosuppressive treatment or patients with immunodeficiency, an adequate immune response may not be elicited. Persons with familial complement deficiencies (for example, C5 or C3 deficiencies) and persons receiving treatments that inhibit terminal complement activation (for example, eculizumab) are at increased risk of invasive disease caused by *Neisseria meningitidis* groups A, C, W, and Y, even if they develop antibodies following vaccination with MenQuadfi. 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. Excipients of known effect: This medicine contains less than 1 mmol sodium (23 mg) per dose essentially, 'sodium-free'.

Interactions: Use with other vaccines: Injection sites on separate limbs (preferably contralateral) 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) + 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). There was no impact on the immune response to MenQuadfi when a meningococcal serogroup B vaccine was co-administered. MenQuadfi can be administered concomitantly with PCV-13. Lower hSBA GMTs on day 30 post-dose for serogroup A have been observed when given concomitantly. The clinical relevance of this observation is unknown. 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. For ages 10 – 17 years, MenQuadfi can be co-administered with diphtheria, tetanus, pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) (Tdap), Tdap and inactivated poliovirus vaccine (Tdap-IPV), and 4-valent human papillomavirus vaccine (recombinant, adsorbed) (4vHPV) or 9-valent HPV vaccine (9vHPV). However, the antibody responses to some of the antigens might be affected by the co-administration. Meningococcal vaccine naïve children and adolescents 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 4vHPV compared to co-administration with 4vHPV vaccine alone (immune response assessed after the full series of HPV was completed). The clinical implications of the observed pertussis antigen responses also observed with other quadrivalent meningococcal conjugate vaccines are unknown. The co-administration of MenQuadfi with Tdap-IPV and 9vHPV in children and adolescents aged 10 – 17 years resulted in lower GMTs and seroresponse rates for serogroup A, lower GMTs for serogroup W, lower responses to inactivated polio types 1 and 3, diphtheria, and anti-HPV types 6 and 58 (immune response assessed after the first dose of 9vHPV) compared to when MenQuadfi was given sequentially with Tdap-IPV and 9vHPV. The clinical implication of the observed reduced titre responses is unclear. Consideration might be given for sequential administration of MenQuadfi with Tdap-IPV and 9vHPV (e.g. for children and adolescents at higher risk). Concomitant administration of MenQuadfi and other vaccines than those listed above has not been studied.

Fertility, pregnancy and lactation: There is limited data on the use of MenQuadfi in pregnant women, MenQuadfi should be used during pregnancy only if the expected benefits for the mother outweigh the potential risks, including those for the foetus. 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: *12 – 23 months:* appetite lost, irritability, drowsiness, abnormal crying, injection site reaction (tenderness/pain, erythema, swelling). *≥2 years of age:* headache, myalgia, malaise, injection site pain. Common: *12 – 23 months:* vomiting, diarrhoea, fever. *≥2 years of age:* fever, injection site reaction (swelling, erythema). Other Serious Adverse Drug Reactions: Uncommon: *12 – 23 months:* urticaria, injection site reaction (pruritus, induration, bruising, rash). *≥2 years of age:* injection site reaction (pruritus, warmth, bruising, rash). Rare: *≥2 years of age:* lymphadenopathy, urticaria, induration (at the injection site). Very Rare: *12 month – ≥2 years of age:* Anaphylaxis. Not known: *12 month – ≥2 years of age:* Hypersensitivity, Febrile convulsions, seizures. Overall, within 7 days after vaccination with a single dose of MenQuadfi, the same injection site and systemic adverse reactions as in paediatrics were observed in older (≥56 years of age) and younger adults (18 – 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. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List price: £31.50

Legal Category: POM

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Marketing Authorisation Holder: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK

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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