Menveo (Meningococcal group A, C, W135 and Y conjugate vaccine) PRESCRIBING INFORMATION

Please find below:

1. **PRESCRIBING INFORMATION for Great Britain (GB)**
2. **PRESCRIBING INFORMATION for Northern Ireland (*which is located below the GB Prescribing Information*)**

PRESCRIBING INFORMATION - Great Britain

Refer to Summary of Product Characteristics (SPC) before prescribing

MENVEO Meningococcal group A, C, W135 and Y conjugate vaccine; powder and solution, for injection. **Composition**: One dose (0,5 ml of the reconstituted vaccine) contains: 10µg Meningococcal group A oligosaccharide, 5µg Meningococcal group C oligosaccharide, 5µg Meningococcal group W-135 oligosaccharide, 5µg Meningococcal group Y oligosaccharide; All conjugated to Corynebacterium diptheriae CRM $_{197}$ protein. **Indications:** Active immunisation against *Neisseria meningitidis* serogroups A, C, W135 and Y for children (from 2 years of age), adolescents and adults at risk of exposure to Neisseria meningitidis groups A, C, W-135 and Y, to prevent invasive disease. The use of this vaccine should be in accordance with official recommendations.

Dosage and administration: a single dose of 0.5 ml intramuscular injection, preferably into the deltoid muscle. It must not be administered intravascularly, subcutaneously or intradermally. Separate injection sites should be used if administering more than one vaccine.

Booster vaccination: Refer to SPC and national recommendations.

Contraindications: Hypersensitivity to the active substance or to any of the excipients, or diphtheria toxoid (CRM_{197}) or a life-threatening reaction after previous administration of a vaccine containing similar components. Postpone use in persons with acute, severe febrile illness.

Precautions: As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in case of rare anaphylactic event following administration of the vaccine. Anxiety-related reactions, including syncope may occur as a psychogenic response to the needle injection. See SPC for full details and advice on use in immunocompromised individuals. Individuals receiving treatment that inhibits terminal complement activation (for example, eculizumab) remain at increased risk of invasive disease even following vaccination with Menveo. Menveo has not been evaluated in persons with thrombocytopenia, bleeding disorders or that are receiving anticoagulant therapy, because of the risk of haematoma. The risk-benefit ratio for persons at risk of haematoma following intramuscular injection must be evaluated by health care professionals. Menveo will not protect against infections caused by any other serogroups of N. meningitidis not present in the vaccine. There are no data on the applicability of the vaccine for post-exposure prophylaxis.

Ability to drive and use machinery: May have a minor influence on the ability to drive and use machines in the 2-3 days following vaccination.

Interactions: see SPC.

Pregnancy and Lactation: Insufficient clinical data on exposed pregnancies are available.

Adverse reactions: See SPC for full details. *Very Common/Common*: sleepiness, headache, nausea, vomiting, diarrhea, eating disorder, rash, irritability, malaise, injection site pain, injection site erythema (≤50 mm), injection site induration (≤50 mm), myalgia, arthralgia, chills, fever ≥38°C.

Serious: hypersensitivity including anaphylaxis, convulsions, injection site cellulitis.

Legal Category: POM. **Presentation and basic NHS cost:** Pack of two vials. MENVEO must be prepared for administration by reconstituting powder (in vial) with solution (in vial), £30.00 per dose. **MA Holder:** GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom. **MA Number:** PLGB 19494/0289. Further information is available from Customer Contact Centre, GlaxoSmithKline, 980 Great West Road, Brentford, Middlesex, TW8 9GS; customercontactuk@gsk.com; Freephone: 0800 221 441.

Ref: PI-0511 (V3). **Date of preparation:** October 2021

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline 0800 221 441

PRESCRIBING INFORMATION – Northern Ireland
Refer to Summary of Product Characteristics (SPC) before prescribing

MENVEO. Meningococcal group A, C, W135 and Y conjugate vaccine; powder and solution, for injection. **Composition**: One dose (0,5 ml of the reconstituted vaccine) contains: 10µg Meningococcal group A oligosaccharide, 5µg Meningococcal group C oligosaccharide, 5µg Meningococcal group W-135 oligosaccharide, 5µg Meningococcal group Y oligosaccharide; All conjugated to Corynebacterium diptheriae CRM $_{197}$ protein. **Indications:** Active immunisation against *Neisseria meningitidis* serogroups A, C, W135 and Y for children (from 2 years of age), adolescents and adults at risk of exposure to Neisseria meningitidis groups A, C, W-135 and Y, to prevent invasive disease. The use of this vaccine should be in accordance with official recommendations.
Dosage and administration: a single dose of 0.5 ml intramuscular injection, preferably into the deltoid muscle. It must not be administered intravascularly, subcutaneously or intradermally.
Separate injection sites should be used if administering more than one vaccine.
Booster vaccination: Refer to SPC and national recommendations.
Contraindications: Hypersensitivity to the active substance or to any of the excipients, or diphtheria toxoid (CRM_{197}) or a life-threatening reaction after previous administration of a vaccine containing similar components. Postpone use in persons with acute, severe febrile illness.
Precautions: As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in case of rare anaphylactic event following administration of the vaccine. Anxiety-related reactions, including syncope may occur as a psychogenic response to the needle injection. See SPC for full details and advice on use in immunocompromised individuals.. Individuals receiving treatment that inhibits terminal complement activation (for example, eculizumab) remain at increased risk of invasive disease even following vaccination with Menveo. Menveo has not been evaluated in persons with thrombocytopenia, bleeding disorders or that are receiving anticoagulant therapy, because of the risk of haematoma. The risk-benefit ratio for persons at risk of haematoma following intramuscular injection must be evaluated by health care professionals. Menveo will not protect against infections caused by any other serogroups of N. meningitidis not present in the vaccine. There are no data on the applicability of the vaccine for post-exposure prophylaxis.
Ability to drive and use machinery: May have a minor influence on the ability to drive and use machines in the 2-3 days following vaccination.
Interactions: see SPC.
Pregnancy and Lactation: Insufficient clinical data on exposed pregnancies are available.
Adverse reactions: See SPC for full details. *Very Common/Common*: sleepiness, headache, nausea, vomiting, diarrhea, eating disorder, rash, irritability, malaise, injection site pain, injection site erythema (≤50 mm), injection site induration (≤50 mm), myalgia, arthralgia, chills, fever ≥38°C.
Serious: hypersensitivity including anaphylaxis, convulsions, injection site cellulitis.
Legal Category: POM. **Presentation and basic NHS cost:** Pack of two vials. MENVEO must be prepared for administration by reconstituting powder (in vial) with solution (in vial), £30.00 per dose. **MA Holder:** GSK Vaccines S.r.l., Via Fiorentina 1, 53100 Siena, Italy. **MA Number:** EU/1/10/614/002, EU/1/10/614/003, EU/1/10/614/004. Further information is available from Customer Contact Centre, GlaxoSmithKline, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom; customercontactuk@gsk.com; Freephone: 0800 221 441.

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