PRESCRIBING INFORMATION
Nimenrix® powder and solvent for solution for injection in pre-filled syringe.
This medicinal product is subject to additional monitoring.
Meningococcal group A, C, W-135 and Y conjugate vaccine. Please refer to the Summary of Product Characteristics (SmPC) before prescribing Nimenrix.

Presentation: After reconstitution one dose (0.5 ml) contains 5 μg Neisseria meningitidis group A polysaccharide, 5 μg Neisseria meningitidis group C polysaccharide, 5 μg Neisseria meningitidis group W-135 polysaccharide and 5 μg Neisseria meningitidis group Y polysaccharide each conjugated to a total of 44 μg of tetanus toxoid carrier protein.

Indications: Active immunisation of individuals from the age of 12 months and above against invasive meningococcal diseases caused by Neisseria meningitidis group A, C, W-135 and Y.

Contraindications: Hypersensitivity to the active substances or to any of the excipients.

Special warnings and precautions for use: Never administer intravascularly, intradermally or subcutaneously. Appropriate medical treatment should always be readily available in case of anaphylactic reactions following administration of the vaccine. Postpone vaccination in acute febrile illness. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Bleeding may occur following intramuscular administration to individuals with thrombocytopenia or any coagulation disorders. A protective immune response may not be elicited in all vaccines especially in patients receiving immunosuppressive treatment. Safety and immunogenicity not assessed in patients with increased susceptibility to meningococcal infections due to conditions such as terminal complement deficiencies and functional asplenia and an adequate immune response may not be elicited in these patients.

Immune responses in toddlers aged 12-14 months: Toddlers aged 12-14 months had similar rabbit complement serum bactericidal assay (rSBA) responses to groups A, C, W-135 and Y at one month after one dose of Nimenrix or at one month after two doses of Nimenrix given two months apart.
A single dose was associated with lower human complement serum bactericidal assay (hSBA) titres to groups W-135 and Y compared with two doses given two months apart. Similar responses to groups A and C were observed after one or two doses (see section 5.1). The clinical relevance of the findings is unknown. If a toddler is expected to be at particular risk of invasive meningococcal disease due to exposure to groups W-135 and Y, consideration may be given to administering a second dose of Nimenrix after an interval of 2 months.
Nimenrix booster vaccination after priming in toddlers, children, adolescents and adults: For subjects primed with Nimenrix aged 1 year and above and boosted with Nimenrix 4 or 5 years later, more than 99.0% of all subjects achieved post-booster SBA titres ≥ 1:8 for both assays (studies MenACWY-TT-062, 048, 059, 088). One month after the booster vaccination, the Geometric Mean Titres (GMTs) elicited were significantly higher than those elicited by age matched naïve control groups, indicating that Nimenrix induces immune memory to groups A, C, W-135, and Y.

Fertility, pregnancy and lactation: Vaccination during pregnancy/ lactation may be considered when the possible advantages outweigh the potential risk.

Undesirable effects: See SmPC for full details. Very common (≥ 1/10) adverse events are appetite loss, irritability, drowsiness, headache, fever, swelling, pain and redness at injection site, fatigue. Common (≥ 1/100 to < 1/10) adverse events are gastrointestinal symptoms (including diarrhoea, vomiting and nausea), injection site haematoma. Uncommon (≥ 1/1000 to < 1/100) adverse events are insomnia, crying, hypoaesthesia, dizziness, pruritus, rash, myalgia, pain in extremity, malaise, injection site reaction (including induration, pruritus, warmth, anaesthesia). Please refer to the SmPC for more information on undesirable effects.

Legal Category: POM. Basic NHS cost: Nimenrix vial for reconstitution with 0.5 ml pre-filled syringe of diluents. 1, £30.00; 10, £300.00. Marketing Authorisation Number: EU/1/12/767/003 (1 pre-filled syringe), EU/1/12/767/004 (10 x 1 pre-filled syringes).
Marketing Authorisation Holder: Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom. Further Information is available on request from: Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK. Tel +44 (0)1304 616161

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard Adverse events should also be reported to Pfizer Medical Information on 01304616161

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