Nimenrix®

Meningococcal groups A, C, W-135 and Y conjugate vaccine

Module 4: Nimenrix® background

This eModule is designed to help you understand what the Nimenrix® vaccine is, how it works and the data that support it. Additionally, learners will be able to identify if they are prescribing the product appropriately.

GET STARTED >>

This eModule is provided to you by Pfizer Ltd. It is not intended to replace your guidelines, protocols and SOPs.

For UK registered healthcare professionals and other relevant decision makers*

References can be found via the buttons on every screen throughout the course, prescribing information and adverse event reporting can be found via buttons on the summary screen.

For full information on Nimenrix, please refer to the Summary of Product Characteristics.

*The ABPI Code of Practice definition of "other relevant decision makers" particularly includes those with an NHS role who could influence in any way the administration, consumption, prescription, purchase, recommendation, sale, supply or use of any medicine but who are not healthcare professionals

PP-NIM-GBR-0280 June 2021

Pfizer Vaccines

Introduction:

Nimenrix® is a meningococcal vaccine that can help prevent infection with *Neisseria meningitidis (N. meningitidis)* serogroups A, C W-135 and Y. This module will provide you with an overview of what Nimenrix® is, how it works and an overview of the most common adverse events.

Learning objectives:

By the end of this Module, you should be able to:

- Describe how Nimenrix® works
- Understand the evidence that supports the use of Nimenrix®
- Identify who Nimenrix® is appropriate for.

Indication and posology of Nimenrix®?

Indication

Nimenrix® is indicated for active immunisation of individuals from the age of 6 weeks against invasive meningococcal diseases (IMD) caused by *Neisseria meningitidis* (*N. meningitidis*) serogroups A, C, W-135 and Y.[1]

Posology[1]

- For infants from 6 weeks to less than 6 months of age: two doses, each of 0.5 mL, should be administered with an interval of 2 months between doses. Infants from 6 months of age, children, adolescents and adults: a single 0.5 mL dose should be administered. An additional primary dose of Nimenrix® may be considered appropriate for some individuals.
- See prescribing information for further details on dosage.
- In infants 6 weeks to <12 months of age (post primary immunisation), a booster dose should be given at 12 months of age with an interval of at least 2 months after the last Nimenrix® vaccination
- A booster dose may be appropriate for some individuals aged 12 months and older who have previously received primary vaccination with Nimenrix® or other conjugate or plain polysaccharide meningococcal vaccines[1]

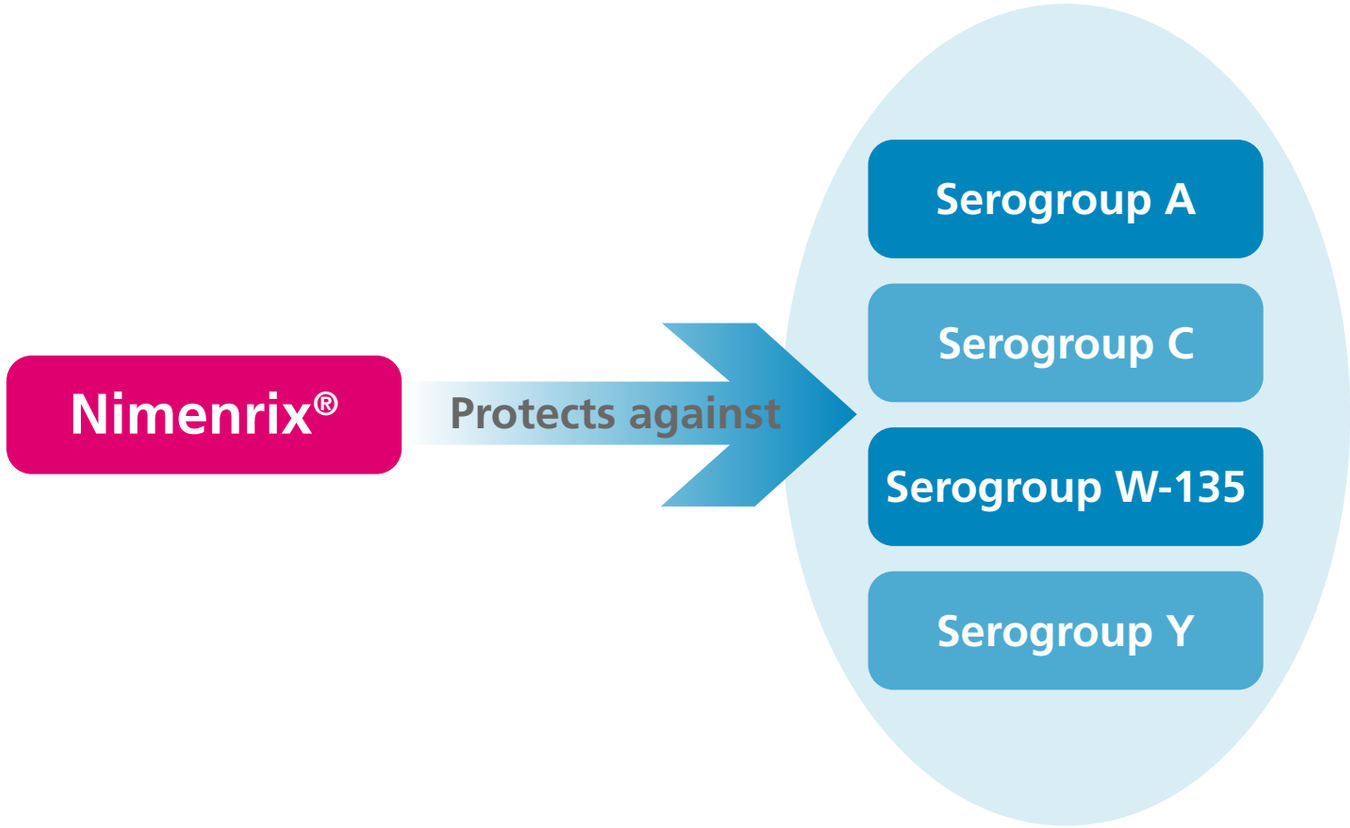
What is Nimenrix®?

Protection

If you remember from Module 1, we learnt that most cases of IMD are caused by six *N. meningitidis* serogroups, including A, B, C, W-135, X and Y.[1]

Nimenrix® is a quadrivalent meningococcal vaccine that helps protect against four *N. meningitidis* serogroups that cause IMD, serogroups A, C, W-135 and Y.[2]

Nimenrix® helps protect against four *N. meningitidis* serogroups associated with IMD[2]



What is Nimenrix®?

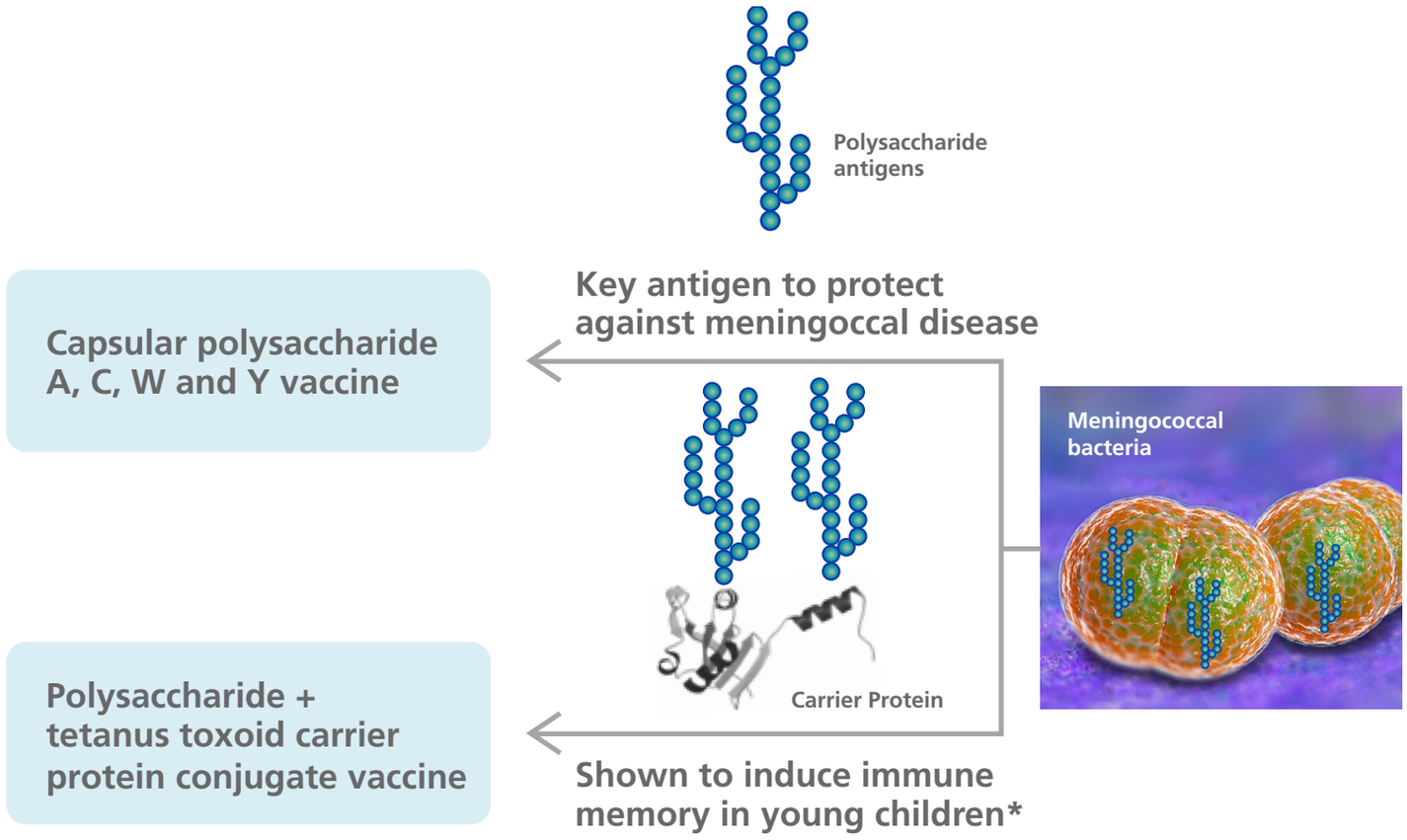
Conjugate vaccine

If you remember from Module 2, conjugate vaccines are made by joining a piece of the polysaccharide capsule that surrounds the *N. meningitidis* bacterium to a protein carrier.[1–3] Compared to purified capsular polysaccharide antigens, conjugation makes the vaccine more able to:[4]

- Produce an immune response (immunogenic)
- Induce an immune memory.

Nimenrix® is a conjugate meningococcal vaccine composed of *N. meningitidis* serogroups A, C, W-135 and Y polysaccharides attached to a tetanus toxoid carrier protein.[5]

Nimenrix® is a conjugate meningococcal vaccine[5]



*Nimenrix® is indicated from 6 weeks of age.

What is Nimenrix®?

Licensure of meningococcal polysaccharide and protein conjugate vaccines

- Licensure of meningococcal vaccines has been based on evidence of an immune response in vaccinated subjects using serum bactericidal activity (SBA) as the immunologic correlate of protection, thus on a surrogate of vaccine efficacy[1]
- The SBA assay measures the ability of the vaccine to generate bactericidal antibodies in the presence of an exogenous complement source[1]

Nimenrix® has demonstrated immunogenicity in those aged from 6 weeks to >65 years

- Nimenrix® induces the production of bactericidal antibodies against capsular polysaccharides of *Neisseria meningitidis* group A, C, W-135 and Y[2]
- The immunogenicity of Nimenrix® has been evaluated in numerous clinical trials and included patients from 6 weeks of age to >65 years of age[2]
- Nimenrix® administered as primary or booster vaccination was highly immunogenic for all four vaccine capsular groups[3]

Safety

Nimenrix® is generally well-tolerated across all age groups. The table shows the very common (≥1/10) and common (≥1/100 to <1/10) adverse reactions from the studies in subjects aged from 6 weeks up to 55 years of and post-marketing experience. Adverse reactions in subjects aged >55 years were similar to those observed in younger adults.[1]

System organ class	Frequency	Adverse reactions
Metabolism and nutrition disorders	Very common	Appetite lost
Psychiatric disorders	Very common	Irritability
Nervous system disorders	Very common	Drowsiness Headache
Gastrointestinal disorders	Common	Diarrhoea Vomiting Nausea*
General disorders and administration site conditions	Very common	Fever Swelling at injection site Pain at injection site Fatigue Redness at injection site
	Common	Injection site haematoma*

*Nausea and injection site haematoma occured at a frequency of uncommon in infants. Rash occurred at a frequency of common in infants.

Contraindications and special warnings[1]

Contraindications

- Hypersensitivity to the active substances or to any of the excipients. (sucrose, trometamol, sodium chloride and water for injection)

Special warnings and precautions for use

- Nimenrix® should not be administered intravascularly, intradermally or subcutaneously.
- Vaccination with Nimenrix® should be postponed in individuals suffering from an acute severe febrile illness. The presence of a minor infection, such as a cold, should not result in the deferral of vaccination.
- Nimenrix® should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these individuals.
- 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 for invasive disease caused by *Neisseria meningitidis* groups A, C, W-135 and Y, even if they develop antibodies following vaccination with Nimenrix®.

For further information on Special Warnings and Precautions please refer to the Nimenrix® Summary of Product Characteristics

Check your understanding

Select the correct answer:

Nimenrix® may be used to vaccinate children from what age?[1]

- From birth
- 6 weeks
- 12 months
- 24 months
- 3 years
- 5 years

Module summary

- Nimenrix® is a quadrivalent meningococcal vaccine indicated for active immunisation of individuals from the age of 6 weeks and above against IMDs caused by *Neisseria meningitidis* serogroups A, C, W-135 and Y.[1]
- For those over 6 months of age, a single dose of Nimenrix® is used for primary immunisation. For infants aged 6 weeks to less than 6 months, primary immunisation consists of two doses, each of 0.5 mL, administered with an interval of 2 months between doses.[1]
- After completion of the primary immunisation course in infants 6 weeks to less than 12 months of age, a booster dose should be given at 12 months of age with an interval of at least 2 months after the last Nimenrix vaccination.[1]
- A booster dose may be appropriate for some individuals aged 12 months and older who have previously received primary vaccination with Nimenrix® or other conjugate or plain polysaccharide meningococcal vaccines.[1]
- Nimenrix® is a conjugate meningococcal vaccine composed of *Neisseria meningitidis* serogroups A, C, W-135 and Y polysaccharides attached to a tetanus toxoid carrier protein.[1]
- Nimenrix® has demonstrated immunogenicity in those aged from 6 weeks to >65 years.[1]
- Nimenrix® is generally well-tolerated across all age groups.[1]