Nimenrix®

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

Module 5: Nimenrix® vaccination process

This eModule is designed to give you practical advice on how to administer Nimenrix®.

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

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Pfizer Vaccines

Introduction:

This module will provide you with an overview of the steps you need to take when administering the Nimenrix® vaccine, including pre-administration checks and the administration process.

Learning objectives:

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

- Understand the steps you need to take before, during and after administering Nimenrix®
- Feel confident when vaccinating with Nimenrix®.

Before administering

It is good practice to prepare a number of items prior to administering Nimenrix®. These include:

Sharps container
You will need a sharps container within easy reach so that you can dispose of any unused vaccine, needles, syringes and waste material in accordance with local requirements.[1,2]

Cotton wool pads
Gentle pressure may need to be applied to the injection site with cotton wool for a few seconds if bleeding occurs.[2]

Anaphylaxis kit
Although anaphylaxis following immunisation is extremely rare, an anaphylaxis kit should always be on hand if anaphylaxis does occur.[2]

Nimenrix®
Nimenrix® should be retrieved from the refrigerator prior to administering the vaccine.[1]

Note: Nimenrix® should be stored in the refrigerator between 2°C and 8°C in its original packaging.
It has a shelf life of 4 years, but, the expiry date on the packaging should always be checked prior to use.[1]

Pre-administration

Before administrating all vaccine administration, vaccinators should ensure that:[1]

- there are no contraindications to the vaccine(s) being given
- the patient or carer is fully informed about the vaccine(s) to be given and understands the vaccination procedure
- the patient or carer is aware of possible adverse reactions and how to treat them.

Before you have administered the Nimenrix® vaccine, you will need to provide the patients with the following information on adverse events

Potential side effects

Very common side-effects (≥1/10) include:[2]

- Fever
- Tiredness (fatigue)
- Headache
- Drowsiness
- Loss of appetite
- Irritability
- Swelling, pain and redness at the injection site.

Common side-effects (≥1/100 to <1/10) include:[2]

- Bruising (haematoma) at the injection site*
- Stomach and digestion problems, such as diarrhoea, vomiting and nausea*
- Rash (infants).

For **uncommon, rare, very rare** and **not known** side-effects, see the Nimenrix® Summary of Product Characteristics or Patient Information Leaflet.

*Nausea and injection site haematoma occurred at a frequency of uncommon in infants

Provide every patient with the Nimenrix® Patient Information Leaflet, then complete the pre-administration checklist

Question 1

Is the recipient allergic to the active substances or other ingredients in the vaccine, i.e. exposure results in symptoms such as itchy skin rash, shortness of breath and swelling of the face or tongue[2]

→ **YES** →

DO NOT VACCINATE[1]
Nimenrix® must not be administered to people with hypersensitivity to the active substances or to any of the excipients in Nimenrix®

→ **NO** → **Go to Question 2**

Provide every patient with the Nimenrix® Patient Information Leaflet, then complete the pre-administration checklist

Question 2

Does the recipient have an acute severe febrile illness (i.e., infection with high fever)[1]

→ **YES** →

Delay Nimenrix® administration until the individual is feeling better

→ **NO** →

Go to Question 3

Provide every patient with the Nimenrix® Patient Information Leaflet, then complete the pre-administration checklist

Question 3

Does the recipient have thrombocytopenia or any other coagulation disorder (i.e., a bleeding condition or bruises easily)

YES →

USE WITH CAUTION[1]
Nimenrix® should be used with caution in individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration

NO → **Go to Question 4**

Provide every patient with the Nimenrix® Patient Information Leaflet, then complete the pre-administration checklist[1]

Question 4

Is the intended recipient receiving immunosuppressive treatment or do they have an immunodeficiency such as a familial complement deficiency

→ **YES** →

Inform them that Nimenrix® may not work in all individuals under these circumstances

→ **NO** →

Go to Question 5

Provide every patient with the Nimenrix® Patient Information Leaflet, then complete the pre-administration checklist

Question 5

Has the recipient read the Nimenrix® Patient Information Leaflet, and thus been informed of the benefits and risks associated with Nimenrix®

→ **NO** → Ask them to read the Nimenrix® Patient Information Leaflet

→ **YES** → **Go to Question 6**

Question 6

Has the recipient (or guardian) given informed consent to receive Nimenrix®

→ **YES** → **VACCINATE**

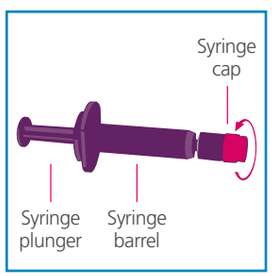
→ **NO** → **DO NOT VACCINATE until informed consent has been obtained**

Pack contents

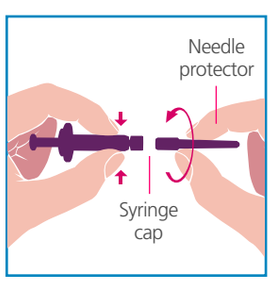
Inside a Nimenrix® box you will find:[1]

- Vial containing Nimenrix® powder
- Solvent in a pre-filled syringe
- Needles, 23G blue, 25G orange[2]

How is Nimenrix® prepared?



1. In one hand, hold the syringe barrel (avoid holding the syringe plunger), and unscrew the syringe cap by twisting it anticlockwise.[1]



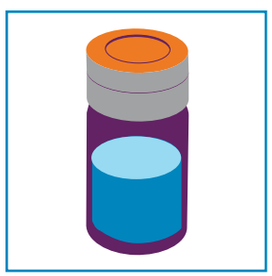
2. Attach the needle to the syringe by twisting.[1]

3. Inject the solvent from the syringe into the powder vial to reconstitute the vaccine components.[1]

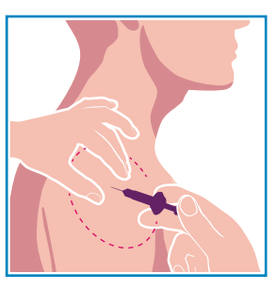
4. After all the solvent has been injected into the vial, shake well to ensure all the powder has dissolved.[1]

   Nimenrix® should be used promptly following reconstitution.[1]

How is Nimenrix® administered?



1. Once reconstituted, inspect the solution. Nimenrix® should appear as a clear, colourless liquid. If there are any foreign particulate matter and/or there is a variation in the physical aspect of the reconstituted Nimenrix prior to administration the vaccine should be discarded.[1]



2. Using a new needle, administer the dose of reconstituted Nimenrix®, as a single intramuscular injection. In infants, the recommended injection site is the anterolateral aspect of the thigh. In individuals from 1 year of age, the recommended injection site is the anterolateral aspect of the thigh or the deltoid muscle.[1]

3. Dispose of any unused product or waste material in accordance with local requirements.[1]

Post-administration

Once you have administered the Nimenrix® vaccine, you will need to provide patients with the following information:

Potential side effects

Very common side-effects (≥1/10) include:[1]

- Fever
- Tiredness (fatigue)
- Headache
- Drowsiness
- Loss of appetite
- Irritability
- Swelling, pain and redness at the injection site.

Common side-effects (≥1/100 to <1/10) include:[1]

- Bruising (haematoma) at the injection site*
- Stomach and digestion problems, such as diarrhoea, vomiting and nausea*
- Rash (infants).

For **uncommon, rare, very rare** and **not known** side-effects, see the Nimenrix® Summary of Product Characteristics or Patient Information Leaflet.

Level of protection

- Nimenrix® will only protect against *Neisseria meningitidis* serogroups A, C, W-135 and Y[1]
- A protective immune response may not be elicited in all vaccinated individuals[1]

*Nausea and injection site haematoma occurred at a frequency of uncommon in infants

Nimenrix® vaccination process

Module summary

- It is good practice to prepare a number of items prior to administering Nimenrix®, including a sharps container, cotton wool pads, anaphylaxis kit and the Nimenrix® vaccine.[1]
- Nimenrix® should be stored in the refrigerator (2– 8°C) in its original packaging. It has a shelf life of 4 years, but, the expiry date on the packaging should always be checked prior to use.[2]
- Nimenrix® should not be given to individuals with certain conditions:[2]
  - Those allergic to the active substances or other ingredients in the vaccine
  - Acute severe febrile illness
- Nimenrix® should be used with caution in individuals with thrombocytopenia or other coagulation disorders.[2]
- Nimenrix® may not work in all individuals under certain circumstances:[2]
  - If the individual has an immunodeficiency
  - If the individual is taking medication that affects their immune system.
  - If the individual is receiving immunosuppressive treatment
- There is a detailed step-by-step administration guide for Nimenrix® that should be followed. This can be found in the Nimenrix® Summary of Product Characteristics or Patient Information Leaflet.[2,3]
- After administration of Nimenrix®, patients should be provided with the following information:[4]
  - Potential side effects