Office of the Nursing & Midwifery Services Director

Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

Continuous Professional Education Programme for Registered Nurses and Midwives to Administer Nimenrix Vaccine (MenACWY)

Under the Medicine Protocol to Students in Second Level Schools (or age equivalent) through a Schools Immunisation Programme

Medicine Protocol

- This Medicine Protocol is a specific written instruction for the administration of Nimenrix Vaccine to Students who may not be individually identified before presentation for vaccination.

Clinical Criteria

MenACWY vaccine active immunisation against and prevention of

Meningococcal Groups A,C, W and Y disease.

Circumstances in which the Medicine Protocol applies

- Meningococcal ACWY immunisation programme is delivered annually by the Health Service Executive (HSE) mainly via School Immunisation Programme, student in first year in second level school or age equivalent to receive a single MenACWY Vaccine.

Inclusion Criteria for Men ACWY Vaccine

- Students in first year of second level schools or equivalent (e.g. home schooled, special schools).

- Students in school outside 1st year who missed the MenACWY vaccine in first year due to medical reasons/ exceptional circumstances and whose parents/legal guardians now request meningococcal vaccine.

- Students with valid consent.

Exclusion Criteria for Men ACWY Vaccine

- Any student who has had an anaphylactic or hypersensitivity reaction to a previous dose of MenACWY or any of the vaccine components or any vaccine containing the same substances
- Any student who has already received a dose of conjugated Men ACWY vaccine aged 10 years or older
- Acute febrile illness – delay vaccination until recovery

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Exclusion criteria

- Students with a contraindication to intramuscular injection (haematological disorder/coagulation disorder e.g. haemophilia, severe thrombocytopenia).

- Students who are immunocompromised either due to disease or treatment.

- The presence of a minor infection such as a mild upper respiratory infection or low grade fever is **not** a contraindication to immunisation.

MenACWY Vaccine: Product Information

Details of the most current and update information of the SmPC and other data is available on the website **https://www.hpra.ie**

Possible Side Effects

Table 1 Tabulated summary of adverse reactions by system organ class		
System Organ Class	**Frequency**	**Adverse reactions**
Metabolism and nutrition disorders	Very common	Appetite lost
Psychiatric disorders	Very common	Irritability
	Uncommon	Insomnia Crying
Nervous system disorders	Very common	Drowsiness Headache
	Uncommon	Hypoaesthesia Dizziness
Gastrointestinal disorders	Common	Diarrhoea Vomiting Nausea*
Skin and subcutaneous tissue disorders	Uncommon	Pruritus Rash**
Musculoskeletal and connective tissue disorders	Uncommon	Myalgia Pain in extremity
General disorders and administration site conditions	Very common	Fever Swelling at injection site Pain at injection site Redness at injection site Fatigue
	Common	Injection site haematoma*
	Uncommon	Malaise Injection site induration Injection site pruritus Injection site warmth Injection site anaesthesia
	Unknown***	Extensive limb swelling at the injection site, frequently associated with erythema, sometimes involving the adjacent joint or swelling of the entire injected limb

*Nausea and Injection site haematoma occurred at a frequency of Uncommon in infants
**Rash occurred at a frequency of Common in infants
***ADR identified post-marketing

- **For a full list of side effects refer to**
  https:// www.hpra.ie

MenACWY Constituents

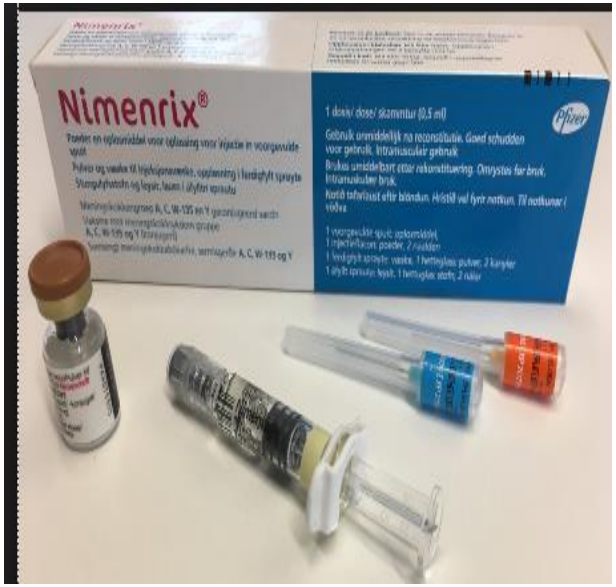
After reconstitution, 1 dose (0.5 ml) contains:

Neisseria meningitidis group A polysaccharide[1]	5 micrograms
Neisseria meningitidis group C polysaccharide[1]	5 micrograms
Neisseria meningitidis group W-135 polysaccharide[1]	5 micrograms
Neisseria meningitidis group Y polysaccharide[1]	5 micrograms
[1]conjugated to tetanus toxoid carrier protein	44 micrograms

- List of excipients
- Powder:
- Sucrose
- Trometamol
- Solvent:
- Sodium chloride
- Water for injections

Nature and contents

Nimenrix is presented as a vial containing Nimenrix powder (contains the MenACWY components) and solvent for solution for injection in pre-filled syringe. The packaging contains two needles, the orange one to be used for reconstitution and the blue one for administration of the vaccine



The vaccine requires reconstitution.

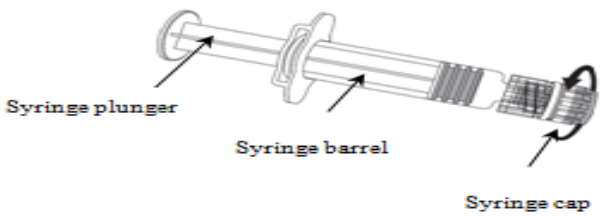
Reconstitution

Instructions for reconstitution of the vaccine with the solvent presented in pre-filled syringe

Nimenrix must be reconstituted by adding the entire content of the pre-filled syringe of solvent to the vial containing the powd

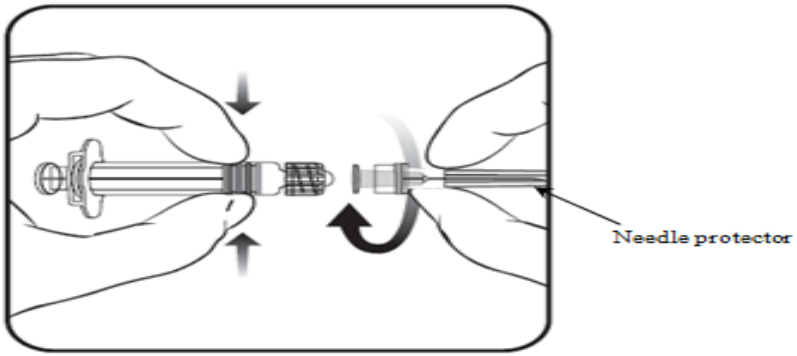
To attach the needle to the syringe, refer to the below picture. However, the syringe provided with Nimenrix might be slightly different (without screw thread) than the syringe described in the picture. In that case, the needle should be attached without screwing.

1. Holding the syringe **barrel** in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise



2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock (See picture).

3. Remove the needle protector, which on occasion can be a little stiff.



4. Add the solvent to the powder. After the addition of the solvent to the powder, the mixture should be well shaken until the powder is completely dissolved in the solvent.

The reconstituted vaccine is a clear colourless solution.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect p administration. In the event of either being observed, discard the vaccine.

After reconstitution, the vaccine should be used promptly.

A new needle should be used to administer the vaccine.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Any Questions?