MenACWY vaccine

Frequently Asked Questions for Health Professionals

From September 2019 the HSE is offering MenACWY vaccine to all students in 1st year of second level education.

What is MenACWY vaccine?

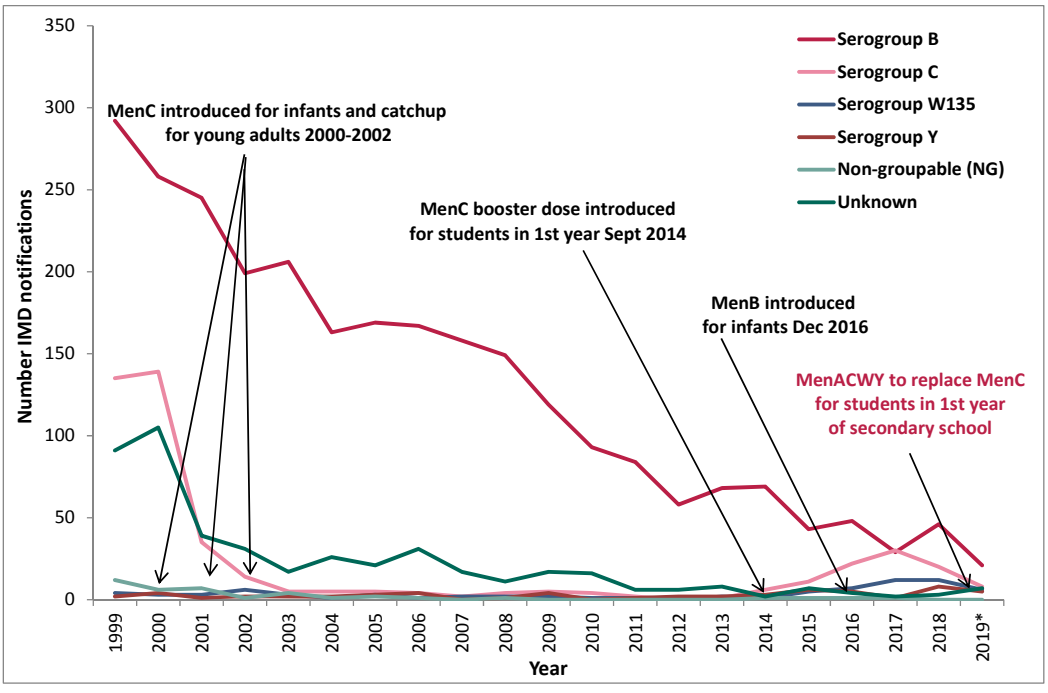
MenACWY being used in Ireland is Nimenrix. This is a conjugate vaccine containing Group A, C, W and Y polysaccharides conjugated to tetanus toxoid carrier protein. The vaccine protects against N. meningitidis Groups A, C, W and Y invasive disease.

Why is MenACWY vaccine recommended for adolescents?

Since 2015 more cases of invasive meningococcal serogroups W and Y disease have been seen in Ireland. Prior to 2015 the annual number of both serogroups was low. Between 1999 and 2014 there was an average of two cases for both serogroups reported per year.

Between 2015 and 2018, a total of 36 serogroup W and 20 serogroup Y cases were reported, giving an average annual notification rate 9 cases per year of serogroup W and for 5 cases per year of serogroup Y. See Figure 1.

Figure 1



(Data from HPSC 27/06/2019)

There have also been increasing cases of Men W disease in several European countries e.g. UK and the

Netherlands in recent years. In view of the emergence of meningococcal serogroups W and Y, the National Immunisation Advisory Committee (NIAC) recommended that one dose of MenACWY vaccine should be given to all students in 1st year of second level education replacing the MenC vaccine in 2019. All students will now receive the Men ACWY vaccine instead of the Men C booster vaccine that has been given in 1st year of second level school since 2014. The Men ACWY vaccine boosts protection against Men C disease as well as giving protection against N. meningitidis Groups A, W and Y invasive disease.

Meningococcal disease is a serious and sometimes fatal illness which can cause meningitis and septicaemia.

Around 10% of those affected will die, for those who survive; many are left with long term sequelae including brain injury or loss of memory, deafness or blindness, and loss of limbs.

Meningococcal disease may occur at any age but the highest rate of disease occurs in children under 5 years of age. There is a second peak of cases in young people aged 15 to 19 years.

Adolescents are also known to have the highest rates of carriage of meningococcal bacteria. As well as providing direct protection, the Men ACWY vaccine prevents carriage of the bacteria and so will also provide some protection to other age groups through herd immunity.

Is MenACWY given to adolescents in other countries?

In September 2015, the Men C vaccine programme for adolescents in the UK was replaced by the introduction of a MenACWY vaccine programme because of the rapid increase in incidence of N. meningitidis Group W invasive disease across all age groups. A catch up programme was also implemented for school leavers and entrants to third level colleges.

In the Netherlands because of a similar increase in N. meningitidis Group W invasive disease all 13–14 year-olds are offered MenACWY vaccine.

MenACWY is also recommended for all adolescents in the US.

When should MenACWY be given in the academic year?

As children will be offered the MenACWY booster to extend protection against N. meningitidis Group C infection and give protection against N. meningitidis Groups A, W, and Y until early adulthood (i.e. some years before peak carriage at 15-19 years of age) the vaccine should be given later in the academic year (i.e. from January 2020).

MenACWY vaccine must be offered to all students with their 2nd dose of HPV vaccine.

As it will be some years before those in 1st year reach the age of peak carriage of meningococci in older teenagers, a high uptake of the MenACWY booster will be vital to produce herd immunity.

Are there any reasons why MenACWY should not be given?

MenACWY vaccine should not be given if there is a history of anaphylaxis to a previous dose of the vaccine or one of its constituents.

In the event of acute severe febrile illness, defer vaccination until recovery.

Note:

The MenACWY vaccine syringe or needle cap does not contain natural rubber.

Therefore a history of anaphylaxis to latex is not a contraindication to the MenACWY vaccine.

What about a child who has had MenACWY vaccine recently?

A student who has had a dose of conjugated MenACWY vaccine at 10 years of age or older does not need an adolescent booster because they already have adequate levels of antibody which should persist until adulthood.

A student who has had a dose of polysaccharide Men ACWY vaccine, even over the age of 10 should still receive a booster of the conjugated Me ACWY vaccine, as this is more effective than the polysaccharide vaccine.

Can other vaccines be given at the same time as MenACWY?

Yes. MenACWY is an inactivated vaccine so this can be administered at the same time as any other live (e.g. MMR) or inactivated (e.g. HPV) vaccine. They should be administered in separate limbs or else in the same limb separated by at least 2.5cm (1 inch).

Can Tdap and MenACWY vaccines be given at the same time?

The Tdap and MenACWY vaccine can be safely given at the same time.

Can Tdap or MenACWY vaccines be given at the same time as HPV vaccine?

The Tdap and MenACWY vaccines can also be given at the same time as the HPV (human papillomavirus) vaccine

Can MenACWY vaccine be given during pregnancy?

MenACWY vaccine may be given to pregnant women when indicated. Considering the severity of meningococcal group disease pregnancy should not preclude vaccination when the risk of exposure is clearly defined.

Does MenACWY vaccine contain thiomersal?

No, MenACWY vaccine does not contain thiomersal.

Is a catch up programme being provided for older students?

The National immunisation Advisory Committee has not recommended a MenACWY vaccine catch up programme for older students.

How safe is MenACWY vaccine?

MenACWY vaccine is safe and well tolerated.

What are the side effects of MenACWY vaccine?

See information from SPC below

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

(Available at https://www.ema.europa.eu/en/documents/product-information/nimenrix-epar-product-information_en.pdf)

Note: MenACWY vaccine protects against Group A, C, W and Y meningococcal disease and does not protect against Group B meningococcal disease.
It is important parents are aware of the signs and symptoms of meningococcal disease.

What MenACWY vaccine is being used in the school programme?

The MenACWY conjugate vaccine used in the school programme is called Nimenrix.

How is Nimenrix presented?

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.

How is Nimenrix reconstituted?

Nimenrix is reconstituted by adding the entire content of the pre-filled syringe of solvent to the vial containing 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 prior to administration. In the event of either being observed, discard the vaccine.

<u>After reconstitution, the vaccine should be used promptly</u>

Nimenrix should only be given intramuscularly.

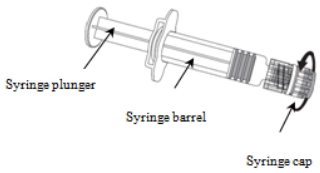
6.6 Special precautions for disposal and other handling

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 powder.

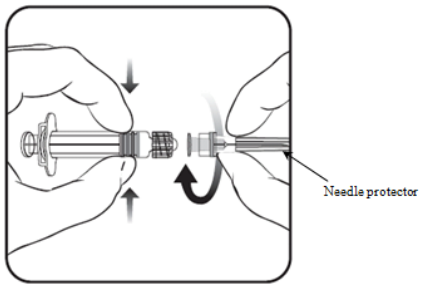
To attach the needle to the syringe, refer to the below picture. However, the syringe provided with Nimenrix might be slightly different (without screw thread) than the syringe described in the picture. In that case, the needle should be attached without screwing.

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.

For more information

See Summary of Product Characteristics and Patient information leaflet at:

Meningococcal group A, C, W and Y conjugate vaccine (Nimenrix) available at

https://www.ema.europa.eu/en/documents/product-information/nimenrix-epar-product-information_en.pdf