Package leaflet: Information for the user

Nimenrix® powder and solvent for solution for injection in pre-filled syringe
Meningococcal group A, C, W-135 and Y conjugate vaccine

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you or your child. Do not pass it on to others.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

This leaflet has been written assuming the person receiving the vaccine is reading it, but it can be given to adults and children so you may be reading it for your child.

What is in this leaflet

1. What Nimenrix is and what it is used for
2. What you need to know before you receive Nimenrix
3. How Nimenrix is given
4. Possible side effects
5. How to store Nimenrix
6. Contents of the pack and other information

1. What Nimenrix is and what it is used for

What Nimenrix is and what it is used for
Nimenrix is a vaccine which helps protect against infections caused by bacteria (germs) called "*Neisseria meningitidis"* types A, C, W-135 and Y.
"Neisseria meningitidis" types A, C, W-135 and Y bacteria can cause serious illnesses such as:
- meningitis - an infection of the tissue that lines the brain and spinal cord.
- septicaemia - an infection of the blood.

These infections are passed easily from person to person and can cause death if not treated.
Nimenrix may be given to adults, adolescents, children and infants over the age of 6 weeks.

How Nimenrix works
Nimenrix helps your body to produce its own protection (antibodies) against the bacteria. These antibodies help protect you against the diseases.
Nimenrix will only protect against infections caused by the bacteria "*Neisseria meningitidis"* types A, C, W-135 and Y.

2. What you need to know before you receive Nimenrix

Nimenrix should not be given if:
- you are allergic to the active substances or any of the other ingredients in this vaccine (listed in section 6).
  Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. **See your doctor immediately if you notice any of these**.

If you are not sure, talk to your doctor or nurse before you receive Nimenrix.

Warnings and precautions:
Check with your doctor or nurse before you receive this vaccine if:

- you have an infection with a high temperature (over 38°C). If this applies to you, the vaccination will not be given until you are feeling better. A minor infection such as a cold should not be a problem. However, talk to your doctor or nurse first.
- you have a bleeding problem or you bruise easily.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before you receive Nimenrix.

Nimenrix may not fully protect everyone who is vaccinated. If you have a weak immune system (such as due to HIV infection or medicines that affect the immune system) you may not get a full benefit from Nimenrix.

Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell the doctor or nurse if you or your child fainted with a previous injection.

Other medicines and Nimenrix
Tell your doctor or nurse if you are taking or have recently taken any other medicines, including other vaccines and medicines obtained without a prescription.

Nimenrix may not work as well if you are taking medicines that affect your immune system.

From age 1 year and above, Nimenrix can be given concomitantly with any of the following vaccines: hepatitis A (HAV) and hepatitis B (HBV) vaccines, measles - mumps - rubella (MMR) vaccine, measles - mumps - rubella - varicella (MMRV) vaccine, 10-valent pneumococcal conjugate vaccine or unadjuvanted seasonal influenza vaccine.

In the second year of life, Nimenrix can also be given concomitantly with combined diphtheria - tetanus - acellular pertussis (DTaP) vaccines, including combination DTaP vaccines with hepatitis B, inactivated poliovirus or *Haemophilus influenzae* type b (HBV, IPV or Hib) such as DTaP-HBV-IPV/Hib vaccine, and 13-valent pneumococcal conjugate vaccine.

In individuals aged 9 to 25 years, Nimenrix can be given concomitantly with human papillomavirus vaccine [Types 16, 18] and a combined diphtheria (reduced antigen content), tetanus and acellular pertussis vaccine.

Whenever possible, Nimenrix and a TT containing vaccine, such as DTaP-HBV-IPV/Hib vaccine, should be co-administered or Nimenrix should be administered at least one month before the TT containing vaccine.

A different injection site will be used for each vaccine.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant, plan to become pregnant or are breast-feeding, you must tell your doctor before receiving Nimenrix.

Driving and using machines
Nimenrix is not likely to affect your ability to drive or use machines. However, do not drive or use any machines if you are feeling unwell.

3. How Nimenrix is given

Nimenrix will be given to you by a doctor or nurse.
Nimenrix is always injected into a muscle, usually in the upper arm or thigh.

<u>Infants from the age of 6 weeks to 12 weeks of age</u>

2 injections given two months apart at e.g. 2 and 4 months of age (the first injection may be given from the age of 6 weeks).
At 12 months of age, an additional injection (booster) will be given.

You will be informed when your child should come back for their next injection. If your child misses a scheduled injection, it is important that you make another appointment.
Make sure your child finishes the complete vaccination course.

Children above 1 year of age, adolescents and adults:
One dose of vaccine should be administered.

Please tell your doctor if you have received a previous injection with another meningococcal vaccine than Nimenrix.

Your doctor will tell you if and when you need an additional dose of Nimenrix, especially if you or your child:

- received your first dose aged 12-23 months and could be at risk of infection caused by *Neisseria meningitidis* types A, C, W-135 and Y
- were aged more than 2 years when first vaccinated and could be at risk of infection caused by *Neisseria meningitidis* type A

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Very common (these may occur with more than 1 in 10 doses of the vaccine):

- fever
- tiredness (fatigue)
- headache
- feeling drowsy
- loss of appetite
- feeling irritable
- swelling, pain and redness where the injection is given.

Common (these may occur with up to 1 in 10 doses of the vaccine):

- bruising (haematoma) where the injection is given
- stomach and digestion problems such as diarrhoea, vomiting and nausea
- rash (infants).

Uncommon (these may occur with up to 1 in 100 doses of the vaccine):

- rash
- crying
- itching
- feeling dizzy
- aching muscles
- pain in the arms or legs
- generally feeling unwell
- difficulty sleeping
- decreased feeling or sensitivity, especially in the skin
- reactions where the injection is given such as itching, a feeling of warmth or numbness or a hard lump.

Not known: frequency cannot be estimated from the available data**:**
- injection site swelling and redness; this may affect a large area of the vaccinated limb

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Nimenrix

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C - 8°C).
- Store in the original package in order to protect from light.
- Do not freeze.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nimenrix contains
- The active substances are:
  - 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

- The other ingredients are:
  - In the powder: sucrose and trometamol
  - In the solvent: sodium chloride and water for injections

What Nimenrix looks like and contents of the pack
Nimenrix is a powder and a solvent for solution for injection.
Nimenrix is supplied as a white powder or cake in a single dose glass vial and a clear and colourless solvent in a pre-filled syringe.

These must be mixed together before use. The mixed vaccine will appear as a clear colourless solution.
Nimenrix is available in packs of 1 or 10 with or without needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Pfizer Europe MA EEIG
Boulevard de la Plaine 17
1050 Bruxelles
Belgium

Manufacturer responsible for batch release:
Pfizer Manufacturing Belgium N.V.
Rijksweg 12
B-2870 Puurs
Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland
Pfizer Healthcare Ireland
Tel: 1800 633 363 (toll free)
+44 (0)1304 616161

Malta
Vivian Corporation Ltd.
Tel: +35621 344610

United Kingdom
Pfizer Limited
Tel: +44 (0) 1304 616161

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/.

Ref: NI 11_0

The following information is intended for healthcare professionals only:

The vaccine is for intramuscular use only. Do not administer intravascularly, intradermally or subcutaneously.

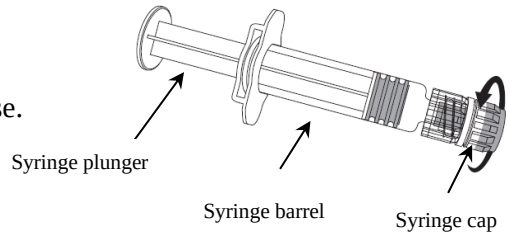
If Nimenrix is co-administered with other vaccines, different injection sites should be used.

Nimenrix should not be mixed with other vaccines.

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

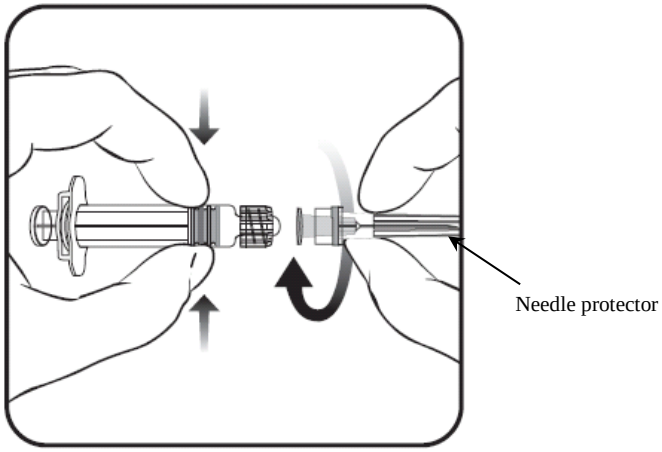
Nimenrix must be reconstituted by adding the entire content of the pre-filled syringe of solvent to the vial containing the powder.
To attach the needle to the syringe, refer to the picture. However, the syringe provided with Nimenrix might be slightly different (without screw thread) than the syringe 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 prior to 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.