Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Nimenrix®, powder and solvent for solution for injection

Each 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

Inactive ingredients and allergens: see section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Nimenrix is intended for active immunization of children aged 6 weeks and older and adults against an invasive meningococcal disease caused by bacteria called *Neisseria meningitidis* types A, C, W-135 and Y.

Therapeutic group: meningococcal vaccine
Nimenrix helps your body to produce its own protection (antibodies) against the bacteria. These antibodies help protect you against meningococcal disease.
Nimenrix will only help protect against infections caused by the bacteria *Neisseria meningitidis* types A, C, W-135 and Y.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You or your child are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6).

Signs of an allergic reaction may include itchy skin rash, difficulty breathing, swelling of the face or tongue. **See your doctor immediately if you get any of these signs**. If you are not sure, talk to your doctor or nurse before you receive Nimenrix.

Special warnings regarding use of the medicine
Before vaccination with Nimenrix, tell your doctor if you or your child have:
- an infection with a high fever (over 38°C). In this case, the vaccination will be postponed until you or your child are feeling better. A minor infection such as a cold should not be a problem. However, talk to your doctor or nurse first.
- bleeding problems or you bruise easily.

If any of the above apply to you or your child (or you are not sure), talk to your doctor or nurse before receiving 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 the full benefit of this vaccine.

Fainting can occur (mostly in adolescents) following, or even before, any syringe and needle injection. Tell your doctor or nurse if you or your child fainted with previous vaccinations.

Drug interactions
If you or your child are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

Nimenrix may not work as well if you or your child are taking medicines that suppress the immune system.

From the age of 6 weeks until the age of one year, Nimenrix can 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 with 10-valent pneumococcal conjugate vaccine.

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

In the second year of life, Nimenrix can be given concomitantly with the following vaccines: diphtheria-tetanus-acellular pertussis (DTaP), 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 with 13-valent pneumococcal conjugate vaccine.

At ages 9 to 25 years, Nimenrix can be given concomitantly with human papillomavirus vaccine (Types 16, 18), and combined diphtheria, tetanus and acellular pertussis vaccine.

Whenever possible, Nimenrix and tetanus toxoid containing vaccines, such as DTaP-HBV-IPV/Hib vaccine, should be co-administered. Alternatively, Nimenrix should be administered at least one month before the tetanus toxoid containing vaccine.

A different injection site should be used for each vaccine.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor before receiving the vaccine.

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

Important information about some of this medicine's ingredients
Nimenrix contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially 'sodium free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by your doctor only.

This vaccine will be given by a doctor or nurse by injection into a muscle, usually in the upper arm or thigh.

Primary immunization

Infants from 6 weeks old up to 6 months old:
Two injections will be given 2 months apart, for example at 2 months and at 4 months of age (the first injection may be given from the age of 6 weeks).

Infants from 6 months old, children, adolescents and adults:
One injection.

Booster dose

Infants from 6 weeks old up to 12 months old:
One booster dose at 12 months of age, at least 2 months after the last dose of Nimenrix.

Previously vaccinated children (12 months and older) and previously vaccinated adults:
Tell your doctor if you have received a previous vaccination with another meningococcal vaccine that is not Nimenrix.
Your doctor will tell you if and when you need an additional dose of Nimenrix, especially if you or your child:

- were first vaccinated at age 6-14 months and could be at risk of infection caused by *Neisseria meningitidis* types Y and W-135.
- were vaccinated more than approximately one year ago and could be at risk of infection caused by *Neisseria meningitidis* type A.
- were first vaccinated at age 12-23 months and could be at risk of infection caused by *Neisseria meningitidis* types A, C, W-135, and Y.

Your doctor or nurse will tell you when you or your child should come back for the next dose. If you or your child misses a scheduled vaccination, it is important that you make another appointment.
Make sure you or your child finishes the complete vaccination course.

Do not exceed the recommended dose.

Adhere to the treatment as recommended by your doctor.

If you or your child have been given an overdose, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Nimenrix may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

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

- fever
- tiredness (fatigue)
- headache
- feeling drowsy

- loss of appetite
- irritability
- swelling, pain and redness at the injection site

Common side effects (may occur with up to 1 in every 10 doses of the vaccine):
- bruising (hematoma) at the injection site
- stomach and digestion problems such as diarrhea, vomiting, and nausea
- rash (in infants)

Uncommon side effects (may occur with up to 1 in every 100 doses of the vaccine):
- rash
- hives
- crying
- itching
- dizziness
- aching muscles
- pain in the arms or legs
- generally feeling unwell
- difficulty sleeping
- decreased feeling or sensitivity, especially in the skin
- reactions at the injection site such as itching, a feeling of warmth or numbness, or a hard lump
- hypersensitivity reaction

Rare side effects (may occur with up to 1 in every 1,000 doses of the vaccine):
- seizures associated with a high temperature

Side effects whose frequency is unknown (the frequency of these effects has not been established yet):
- injection site swelling and redness; this may affect a large area of the vaccinated limb
- enlarged lymph nodes
- severe allergic reaction (anaphylaxis)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link:
https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in the refrigerator (2°C-8°C). Do not freeze.
- Store in the original package in order to protect from light.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
- In the powder: trometamol, sucrose
- In the solvent: sodium chloride, water for injections

What the medicine looks like and contents of the pack:
Nimenrix is marketed as a powder and a solvent for preparing a solution for injection.

The package contains a white powder or cake in a single dose glass vial and a clear and colorless solvent in a pre-filled syringe.

The powder must be mixed with the solvent before use. After being mixed, a clear colorless solution will be obtained.

Nimenrix is marketed in packs of 1 or 10 with or without needles. The needles are sterile and are for single use.

Not all pack sizes may be marketed. The pack may contain a needle.

Registration holder's name and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach, 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
150-74-33816

Revised in 12/2024.

The following information is intended for medical or healthcare professionals only:

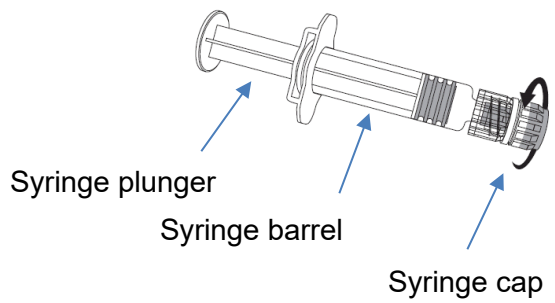
The vaccine is for intramuscular use only. Do not administer intravascularly, intradermally or subcutaneously.

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

Nimenrix should not be mixed with other vaccines.

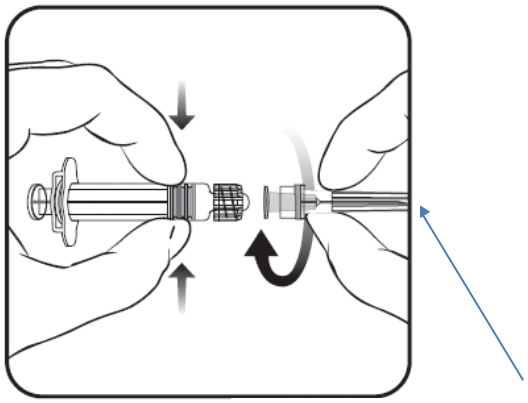
Instructions for reconstitution of the vaccine with the solvent provided in pre-filled syringe:
Nimenrix must be reconstituted by adding the entire content of the pre-filled syringe of solvent to the vial containing the powder.
To attach the needle to the syringe, refer to the picture. However, the syringe 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.



Needle protector

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 colorless 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 vaccine or waste material should be disposed of in accordance with local requirements.