

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

NIMENRIX®

Meningococcal polysaccharide groups A, C, W-135 and Y conjugate vaccine Powder and diluent for solution for injection

Read this carefully before you/your child receive **NIMENRIX**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your/your child's medical condition and treatment and ask if there is any new information about **NIMENRIX**.

What is NIMENRIX used for?

- NIMENRIX is a vaccine that may be given to infants from the age of 6 weeks, children, adolescents and adults up to 55 years old to prevent illness caused by *Neisseria meningitidis* types A, C, W-135 and Y bacteria (germs).

Neisseria meningitidis types A, C, W-135 and Y bacteria most often cause meningitis (infection of the tissue lining the brain) and septicemia (infection of the blood). These diseases can be highly infectious and are sometimes fatal.

As with all vaccines, NIMENRIX may not fully protect all people who are vaccinated.

NIMENRIX will only protect against infections caused by groups of *Neisseria meningitidis* for which the vaccine has been developed.

How does NIMENRIX work?

The vaccine works by causing the body to produce its own protection (antibodies) against these bacteria. The vaccine cannot cause these diseases.

What are the ingredients in NIMENRIX?

Medicinal ingredients: Each 0.5 mL dose contains 5 micrograms of each of the *Neisseria meningitidis* capsular polysaccharides A, C, W-135 and Y each coupled to tetanus toxoid as a carrier protein.

Non-medicinal ingredients:

- Powder: sucrose, trometamol
- Diluent: sodium chloride, water for injections

NIMENRIX comes in the following dosage forms:

Powder (in a single dose vial) and diluent for solution for injection (in a pre-filled syringe).

Do not use NIMENRIX if:

- You/your child have previously had any allergic reaction to NIMENRIX, or to any ingredient contained in NIMENRIX. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you/your child receive NIMENRIX. Talk about any health conditions or problems you/your child may have, including if:

- you or your child have/has a severe infection with a high temperature. In these cases, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your health professional first.
- you or your child have/has a bleeding problem or bruise(s) easily.
- you or your child have/has a weakened immune system, for example due to HIV infection or complement deficiencies or due to medicines that suppress the immune system (for example, eculizumab). You or your child may not get the full benefit from NIMENRIX, or may remain at increased risk for disease caused by meningococcal groups A, C, W-135 and Y bacteria even if you develop antibodies following vaccination with NIMENRIX.
- you are pregnant or breastfeeding.

Other warnings you should know about:

Fainting can occur following, or even before, any needle injection, therefore tell your health professional if you/your child fainted with a previous injection.

Tell your healthcare professional about all the medicines you/your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Please tell your health professional if you/your child have/has recently received any other vaccine.

NIMENRIX can be given at the same time as other vaccines such as hepatitis A and hepatitis B vaccines, measles-mumps-rubella vaccine, measles-mumps-rubella-varicella vaccine, 10-valent pneumococcal conjugate vaccine or unadjuvanted seasonal influenza vaccine.

In the first two years of life, NIMENRIX can also be given at the same time or at least one month before a combined diphtheria-tetanus-acellular pertussis vaccine, including combination diphtheria-tetanus-acellular pertussis vaccine with hepatitis B, inactivated poliovirus or *Haemophilus influenzae* type b, such as DTaP/IPV/Hib/HepB vaccine, and 13-valent pneumococcal conjugate vaccine.

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

A different injection site will be used for each vaccine.

The following may interact with NIMENRIX:

NIMENRIX may not work as well if you/your child are/is taking medicines that reduce the effectiveness of your/your child's immune system to fight infection.

How NIMENRIX is given:

Usual dose:

Your health professional will give NIMENRIX as an injection into the muscle, in the upper arm or thigh.

NIMENRIX is given as an injection of 0.5 mL.

Primary immunization

Infants from 6 weeks to less than 6 months of age

Your child will receive two injections given 2 months apart at e.g., 2 and 4 months of age (the first injection may be given from the age of 6 weeks).

From 6 months to 55 years of age

Infants 6 months and older, children, adolescents and adults should receive one dose of vaccine.

Booster doses

Infants from 6 weeks to less than 12 months of age

One booster dose at 12 months of age, at least 2 months after the last dose of NIMENRIX.

Previously vaccinated individuals 12 months of age and older

Please tell your doctor if you or your child have received a previous dose of NIMENRIX or another meningococcal vaccine.

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 at age 6-14 months and could be at particular risk of infection caused by *Neisseria meningitidis* types W-135 and/or Y
- received your dose more than approximately one year ago and could be at risk of infection caused by *Neisseria meningitidis* type A
- received your first dose at age 12-23 months and could be at particular risk of infection caused by *Neisseria meningitidis* types A, C, W-135 and Y

You will be informed when you or your child should come back for the next injection.

Overdose:

If you think you, or a person you are caring for, have received too much NIMENRIX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you or your child misses a scheduled injection, it is important that you make another appointment.

Make sure that you or your child finishes the complete vaccination course.

What are possible side effects from using NIMENRIX?

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of NIMENRIX causing serious harm is extremely small. The small risks associated with NIMENRIX are much less than the risk associated with getting the disease.

In infants, adolescents and adults, very common side effects (in more than 1 in 10 doses of the vaccine) after having NIMENRIX are loss of appetite, irritability, drowsiness, headache, fever, swelling, pain and redness at the injection site and fatigue.

Common side effects (in more than 1 in 100 and up to 1 in 10 doses of the vaccine) after having NIMENRIX are gastrointestinal symptoms including diarrhea, vomiting and nausea, injection site hematoma, and rash (infants).

Uncommon side effects (in more than 1 in 1,000 and up to 1 in 100 doses of the vaccine) after having NIMENRIX are insomnia, crying, dizziness, decreased feeling or sensitivity especially in the skin, itching, rash, hives, aching muscles, pain in extremity (pain in the limb), generally feeling unwell, hypersensitivity, and injection site reaction (such as a hard lump at the injection site, itching warmth and loss of feeling).

Rare side effect (in more than 1 in 10,000 and up to 1 in 1,000 doses of the vaccine) after having NIMENRIX is febrile convulsion.

The most common side effects reported during clinical trials usually lasted only one to two days and were not usually severe.

The following additional side effect has been reported during marketed use and so the frequency cannot be estimated from the available data: large swelling of the vaccinated limb associated with redness.

Do not be alarmed by this list of possible side effects. It is possible that you or your child will have no side effects from vaccination.

These are not all the possible side effects you may have when taking NIMENRIX. If you experience any side effects not listed here, tell your health professional.

Tell your health professional as soon as possible if you or your child does not feel well after receiving NIMENRIX.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your health professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Pfizer Canada ULC cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Keep out of reach and sight of children. Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original package in order to protect from light.

If you want more information about NIMENRIX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website <https://www.pfizer.ca>, or by calling 1-800-463-6001.

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