PART III: CONSUMER INFORMATION

NIMENRIX®
Meningococcal polysaccharide groups A, C, W-135 and Y conjugate vaccine

This leaflet is part III of a three-part "Product Monograph" published when NIMENRIX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about NIMENRIX. Contact your health professional if you have any questions about the vaccine.

ABOUT THIS VACCINE

What the vaccine is 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.

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

When it should not be used:
Please see WARNINGS AND PRECAUTIONS section.

What the medicinal ingredient is:
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.

What the important non-medicinal ingredients are:
NIMENRIX contains the following non-medicinal ingredients:

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

What dosage forms it comes in:
NIMENRIX is presented as a powder and diluent for solution for injection.

WARNINGS AND PRECAUTIONS

NIMENRIX should not be given if you have previously had any allergic reaction to NIMENRIX, or 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.

BEFORE you use NIMENRIX talk to your health professional 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.

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

INTERACTIONS WITH THIS VACCINE

Please tell your health professional if you/your child are/is taking or have/has recently taken any other medicines, including medicines obtained without a prescription or have/has recently received any other vaccine.

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.

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-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.

A different injection site will be used for each vaccine.

PROPER USE OF THIS VACCINE

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 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. 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.

Overdose:

In case of overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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 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 doses of the vaccine) after having NIMENRIX are insomnia, crying, dizziness, decreased feeling or sensitivity especially in the skin, itching, rash, aching muscles, pain in extremity (pain in the limb), generally feeling unwell, and injection site reaction (such as a hard lump at the injection site, itching warmth and loss of feeling).

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.

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

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.

This is not a complete list of side effects. For any unexpected effects while taking NIMENRIX, contact your health professional.

HOW TO STORE IT

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.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects case reports on adverse events following immunization.

For health care professionals:
If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events following Immunization (AEFI) Form and send it to your local Health Unit in your province/territory.

For the General Public:
Should you experience an adverse event following immunization, please ask your doctor, nurse, or pharmacist to complete the Adverse Events following Immunization (AEFI) Form.

If you have any questions or have difficulties contacting your local health unit, please contact Vaccine Safety Section at Public Health Agency of Canada:

By toll-free telephone: 1-866-844-0018
By toll-free fax: 1-866-844-5931
By email: caefi@phac-aspc.gc.ca
At the following website:
http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php

By regular mail:
The Public Health Agency of Canada
Vaccine Safety Section
130 Colonnade Road
Ottawa, Ontario
K1A 0K9 Address Locator 6502A

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying the Public Health Agency of Canada. The Public Health Agency of Canada does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at www.pfizer.ca or by contacting the sponsor,
Pfizer Canada ULC
at: 1-800-463-6001 (Medical Information)

This leaflet was prepared by Pfizer Canada ULC

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