IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Menactra®

Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine

This leaflet is Part III of a three-part "Product Monograph" published when Menactra® was approved for sale in Canada. It gives you a summary of important information about Menactra®. It does not tell you everything about the vaccine. Contact your doctor, nurse or pharmacist if you have any questions**.**

ABOUT THIS VACCINE

What the vaccine is used for:

Menactra® is a vaccine that is used to prevent meningococcal diseases and/or septicemia (blood poisoning) caused by bacteria called *Neisseria meningitidis* (serogroups A, C, Y and W-135). This vaccine may be given to persons 9 months through 55 years of age.

Meningococcal diseases are very serious. Approximately 10% of people who get a meningococcal disease will die. Death may occur within 24-48 hours after symptoms appear. Of those who survive the disease, some (11 to 19%) will be permanently disabled. There are three kinds of meningococcal disease: meningococcemia, meningococcal meningitis and meningococcal pneumonia. Meningococcemia is the most serious form of the disease where up to 40% of those affected die.

What it does:

Menactra® causes your body to produce its own natural protection against meningococcal diseases. After you receive the vaccine, your body begins to make substances called antibodies. Antibodies help your body to fight disease. If a vaccinated person comes into contact with one of the germs that cause this disease, the body is usually ready to destroy it.

The amount of time it takes for your body to develop enough antibodies to protect you from meningococcal diseases can vary. It can take several days to a few weeks after your vaccination.

The great majority of people who get vaccinated with Menactra® will produce enough antibodies to protect them against meningococcal diseases (groups A, C, Y and W-135). However, as with all vaccines, 100% protection cannot be guaranteed.

When it should not be used:

Do not give Menactra® to:

- persons who are known to have a severe allergy to any ingredient in the vaccine or its container, or who have had a severe allergic reaction after receiving a vaccine that contained similar ingredients.

What the medicinal ingredient is:

Each 0.5 mL dose of Menactra® contains: meningococcal A, C, Y and W-135 polysaccharides conjugated to diphtheria toxoid protein carrier.

What the important non-medicinal ingredients are:

The stopper for the single dose vial does not contain dry natural rubber latex.

What dosage forms it comes in:

Menactra® is a liquid vaccine that is injected into a muscle. A single dose is 0.5 mL.

WARNINGS AND PRECAUTIONS

If you or your child has any of the following conditions, talk to your doctor or nurse BEFORE you or your child receives Menactra®:

- **A high fever or serious illness.** Delay the vaccination until the person is better.
- **An allergy to any component of the vaccine or the container.**

- **Pregnant or nursing women.** It is important that you understand the risks and benefits of vaccination. Menactra® should be given to a pregnant woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.

- **A weakened immune system.** The vaccine may provide you with a lower level of protection than it does for people with healthy immune systems. If possible, try to postpone the vaccination until after you have completed the treatment that affects your immune system.

- **A bleeding disorder or taking blood-thinning medications.** Tell the person giving you the injection about your condition. The injection must be done carefully to prevent excessive bleeding.

- **A previous history of a serious nervous system disorder called Guillain-Barré syndrome (GBS).** These persons may be at increased risk of GBS after receiving Menactra®.

- **Fainted with a previous injection.** Fainting can occur following vaccination. Appropriate measures should be taken to prevent falling injury.

- If removal of the spleen (splenectomy) is planned, Menactra® should be given, if possible, 10 to 14 days before surgery.

INTERACTIONS WITH THIS VACCINE

DO NOT mix Menactra® with other vaccines or medicinal products in the same syringe.

Menactra® may be given at the same time but at separate sites with:

- tetanus and reduced-dose diphtheria vaccine
- *Salmonella typhi* Vi Capsular Polysaccharide Vaccine
- Measles, Mumps, Rubella, Varicella vaccines
- Pneumococcal conjugate vaccine
- Hepatitis A vaccine
- *Haemophilus influenzae* type b vaccine

PROPER USE OF THIS VACCINE

For infants and toddlers 9 months of age through 23 months of age, 2 single doses (0.5 mL) given at least 3 months apart are recommended. For persons 2 years of age and over, a single dose (0.5 mL) is recommended.

The vaccination should be given in the muscle, preferably in the deltoid (shoulder) region.

Overdose:

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

Missed Dose:

Not applicable to this vaccine.

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 Menactra® causing serious harm is extremely small. The small risks associated with Menactra® are much less than the risks associated with getting the disease.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after having Menactra®.

Serious side effects are extremely rare.

Some people who receive Menactra® may have side effects such as redness or pain at the site of injection, headache or fever, that in majority are mild in intensity. Common side effects in infants include fever, increased crying, fussiness, vomiting, drowsiness and loss of appetite. These side effects usually go away within a few days.

This is not a complete list of side effects. For any unexpected effects while taking Menactra®, contact your doctor or pharmacist.

HOW TO STORE IT

Store the vaccine in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze.** Throw away the product if it has been exposed to freezing.

Do not use after the expiration date.

Keep out of reach of children.

REPORTING SUSPECTED SIDE EFFECTS

To monitor vaccine safety, the Public Health Agency of Canada collects information on serious and unexpected adverse events following vaccination. If you suspect you have had a serious or unexpected event following receipt of a vaccine you may notify the Public Health Agency of Canada:

By toll-free telephone: 613-954-5590
(1-866-844-0018)
By toll-free fax: 613-954-9874
(1-866-844-5931)
By email: caefi@phac-aspc.gc.ca

By regular mail:
The Vaccine Safety Section
Centre for Immunization & Respiratory Infectious Diseases
Public Health Agency of Canada
130 Colonnade Road
A/L 6502A
Ottawa, Ontario
K1A 0K9

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.sanofipasteur.ca

You may also contact the vaccine producer, Sanofi Pasteur Limited, for more information.

Telephone: 1-888-621-1146 (no charge) or 416-667-2779 (Toronto area).

Business hours: 7:30 a.m. to 7:30 p.m. Eastern Time, Monday to Friday.

This leaflet was prepared by Sanofi Pasteur Limited.

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