

PART III: CONSUMER INFORMATION

**PNEUMOVAX<sup>®</sup> 23**

(pneumococcal vaccine, polyvalent, MSD Std.)

This leaflet is part III of a three-part "Product Monograph" published when PNEUMOVAX<sup>®</sup> 23 was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PNEUMOVAX<sup>®</sup> 23. Contact your doctor or pharmacist if you have any questions about the vaccine.

**ABOUT THIS VACCINE**

What the vaccine is used for:

PNEUMOVAX<sup>®</sup> 23 is an injectable vaccine to help prevent infections, such as pneumonia and bacteremia (severe infection in the blood), caused by certain types of pneumococcal bacteria.

The vaccine can be administered routinely to persons 50 years of age or older. The vaccine can also be administered to persons 2 years of age and older if:

- they have chronic illnesses (e.g., heart disease, lung disease, liver disease or diabetes mellitus), alcoholism or cerebrospinal fluid leaks.
- they do not have a spleen or have a spleen that does not function properly.
- they have HIV infection, Hodgkin's disease, lymphoma, multiple myeloma, leukemia, generalized malignancy, chronic renal failure or nephrotic syndrome, are receiving cancer chemotherapy or other immunosuppressive therapy (including corticosteroids) or have organ or bone marrow transplantation.
- they are living in special environments or social settings with an increased risk of pneumococcal infection.

A second dose of the vaccine may be recommended at a later date if you are at high risk for a pneumococcal infection.

What it does:

Your doctor has recommended or administered PNEUMOVAX<sup>®</sup> 23 to help protect you or your child against pneumococcal infections caused by the most common types of pneumococci.

Pneumococcal infection is a leading cause of death throughout the world and is a major cause of

pneumonia, swelling of the coverings on the brain and spinal cord (meningitis), middle ear infections (otitis media), and a severe infection in the blood (bacteremia). These problems are more likely to occur in older people and those with certain diseases that make them more susceptible to a pneumococcal infection.

When it should not be used:

PNEUMOVAX<sup>®</sup> 23 should not be used by anyone who:

- is allergic to any of the ingredients in the vaccine. A list of ingredients can be found below.
- has had an allergic reaction from a previous dose of the vaccine.

What the medicinal ingredient is:

Each dose of vaccine contains 25 micrograms of each of 23 types of polysaccharide from bacteria known as pneumococci. These have been highly purified to make them suitable for you or your child to be given them as an injection. The 23 types of pneumococcal polysaccharide in the vaccine are types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F and 33F.

What the important nonmedicinal ingredients are:

PNEUMOVAX<sup>®</sup> 23 also contains the following inactive ingredients: phenol, sodium chloride and water for injection.

What dosage forms it comes in:

PNEUMOVAX<sup>®</sup> 23 is supplied as a single-dose vial containing 0.5 mL of liquid vaccine. A multi-dose vial containing five 0.5 mL doses can be made available for mass immunization programs.

**WARNINGS AND PRECAUTIONS**

Before you or your child receive PNEUMOVAX<sup>®</sup> 23, it is very important to tell your healthcare provider:

- if you or your child are allergic to any component of the vaccine; and
- about any medical problem you or your child have or have had, including any allergies.

### Use in children

PNEUMOVAX<sup>®</sup> 23 can be used in children 2 years of age and older. It is not recommended for use in children below 2 years of age.

### Use in pregnancy

It is not known whether the vaccine is harmful to an unborn baby when administered to a pregnant woman. Tell your doctor if you are pregnant. Your doctor will decide if you should receive PNEUMOVAX<sup>®</sup> 23.

### Use in breast-feeding

Tell your doctor if you are breast-feeding or intend to breast-feed. Your doctor will decide if you should receive PNEUMOVAX<sup>®</sup> 23.

### Use in elderly

Individuals 65 years and older may not tolerate medical interventions as well as younger individuals. Therefore, a higher number and/or a greater severity of reactions in some older individuals cannot be ruled out. Severe side effects after vaccination have been reported in some frail elderly people who have other serious medical problems.

### Can I drive or operate machinery following vaccination with PNEUMOVAX<sup>®</sup> 23?

There is no information to suggest that PNEUMOVAX<sup>®</sup> 23 affects your ability to drive or operate machinery.

### What other important information about PNEUMOVAX<sup>®</sup> 23 should I know?

As with other vaccines, PNEUMOVAX<sup>®</sup> 23 may not fully protect all those who receive it.

## INTERACTIONS WITH THIS VACCINE

PNEUMOVAX<sup>®</sup> 23 has been administered at the same time as influenza vaccines with satisfactory results. Your doctor will decide the vaccination schedule.

PNEUMOVAX<sup>®</sup> 23 should not be given at the same time as ZOSTAVAX<sup>®</sup> (zoster vaccine live, attenuated [Oka/Merck]). For more information, talk to your doctor.

## PROPER USE OF THIS VACCINE

### Usual dose:

PNEUMOVAX<sup>®</sup> 23 is given by intramuscular or subcutaneous injection.

The dose of the vaccine is the same for everyone.

A second dose of PNEUMOVAX<sup>®</sup> 23 is not routinely recommended. However, for persons at the highest risk of serious pneumococcal infection, a second dose of the vaccine may be recommended. Your doctor will decide if and when you need a second dose of PNEUMOVAX<sup>®</sup> 23.

### 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

Any vaccine may have unintended or undesirable effects, so-called side effects. The most common side effects reported with PNEUMOVAX<sup>®</sup> 23 are soreness, redness, swelling, warmth and hardening at the injection site and fever.

Other side effects may also occur rarely (e.g., fatigue, chills, feeling unwell, nausea, vomiting, enlarged and/or inflamed lymph glands, arthritis, headache, allergic reaction, joint pain, muscle pain, altered skin sensation, hives or rash, pain, decreased ability to move limb, and seizures in children due to fever), and some of these may be serious.

Reactions at the site where you get the shot may be more common and intense after a second shot than after the first shot.

Your doctor has a more complete list of side effects.

Tell your doctor promptly about any of these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

*This is not a complete list of side effects. For any unexpected effects while taking PNEUMOVAX<sup>®</sup> 23, contact your doctor or pharmacist.*

## HOW TO STORE IT

Store refrigerated at 2–8°C.

All vaccines must be discarded after the expiration date.

## 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 e-mail: [caefi@phac-aspc.gc.ca](mailto:caefi@phac-aspc.gc.ca)

Web:

<http://www.phac-aspc.gc.ca/im/vs-sv/index-eng.php>

Mail:

The Public Health Agency of Canada  
Vaccine Safety Section  
130 Colonnade Road, A/L 6502A  
Ottawa, ON K1A 0K9

or at Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete an Adverse Events following Immunization (AEFI) Form and:
  - Fax toll-free to 1-800-369-3090, or
  - Mail to: Merck Canada Inc.  
Pharmacovigilance  
P.O. Box 1005  
Pointe-Claire–Dorval, QC  
H9R 4P8

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

## MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.merck.ca> or by contacting the sponsor, Merck Canada Inc., at: 1-800-567-2594.

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