

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PNEUMOVAX® 23

(pneumococcal vaccine, polyvalent, MSD Std.)

Read this carefully before you or your child are vaccinated with **PNEUMOVAX® 23**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PNEUMOVAX® 23**.

What is PNEUMOVAX® 23 used for?

PNEUMOVAX® 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.

PNEUMOVAX® 23 is for people 50 years of age and older. It is also for people who are 2 years of age and older if they have certain medical conditions that put them at increased risk for infection.

Illnesses or health problems may allow these germs to spread into the blood, lungs, or brain where they can cause serious diseases such as:

- An infection in the blood
- A lung infection (pneumonia) that can also come with an infection in the blood
- An infection of the coverings of the brain and spinal cord (meningitis).

PNEUMOVAX® 23 may not protect everyone who gets it. It will not protect against diseases that are caused by bacteria types that are not in the vaccine.

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

How does PNEUMOVAX® 23 work?

Your doctor has recommended or administered PNEUMOVAX® 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.

What are the ingredients in PNEUMOVAX® 23?

Medicinal ingredients: 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.

Non-medicinal ingredients: PNEUMOVAX® 23 also contains the following inactive ingredients: phenol,

sodium chloride and water for injection.

PNEUMOVAX® 23 comes in the following dosage forms:

PNEUMOVAX® 23 is supplied as prefilled syringes containing 0.5 mL of liquid vaccine.

Do not use PNEUMOVAX® if:

PNEUMOVAX® 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 above.
- has had an allergic reaction from a previous dose of the vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you or your child take PNEUMOVAX® 23. Talk about any health conditions or problems you or your child may have or have had, including:

- allergies to any component of the vaccine; and
- any medical problem, including any allergies.

Use in children

PNEUMOVAX® 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® 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® 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.

Other warnings you should know about:

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

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

The following may interact with PNEUMOVAX® 23:

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

PNEUMOVAX® 23 should not be given at the same time as ZOSTAVAX® (zoster vaccine live, attenuated [Oka/Merck]). For more information about these vaccines, talk to your doctor or health care provider, because it may be better to get these vaccines at least 4 weeks apart.

How to take PNEUMOVAX® 23:

PNEUMOVAX® 23 will be given to you or your child by a healthcare professional in a healthcare setting.

Usual dose:

PNEUMOVAX® 23 is given by intramuscular or subcutaneous injection.

The dose of the vaccine is the same for everyone.

A second dose of PNEUMOVAX® 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® 23.

Overdose:

If you think you, or a person you are caring for, have received too much PNEUMOVAX® 23, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

PNEUMOVAX® 23 is given as a single dose. Your doctor will decide if and when you need a second dose of PNEUMOVAX® 23.

What are possible side effects from using PNEUMOVAX® 23?

These are not all the possible side effects you or your child may have when receiving PNEUMOVAX® 23. If you or your child experience any side effects not listed here, tell your healthcare professional.

The most common side effects reported with PNEUMOVAX® 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.

Tell your health care provider or get emergency help right away if you get any of the following problems after vaccination because these may be signs of an allergic reaction or other serious conditions:

- difficulty breathing
- wheezing
- rash
- hives

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.

If you or your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with daily activities, tell your healthcare 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 [Sponsor Name] 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/aefi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store refrigerated at 2–8°C.

All vaccines must be discarded after the expiration date.

Keep out of reach and sight of children.

If you want more information about PNEUMOVAX® 23:

- 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 www.merck.ca, or by calling at 1-800-567-2594.

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