PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

PNEUMOVAX® 23

(pneumococcal vaccine, polyvalent, MSD Std.)

Solution for injection

Active Immunizing Agent Against Infections Caused by Pneumococci

ATC code: J07AL01

Merck Canada Inc.

16750 route Transcanadienne
Kirkland, QC H9H 4M7
Canada

www.merck.ca

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Sections or subsections that are not applicable at the time of authorization are not listed.

PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

PNEUMOVAX® 23 is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F) in individuals 50 years of age or older and individuals aged ≥ 2 years who are at increased risk for pneumococcal disease.

PNEUMOVAX® 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

1.1 Pediatrics

Pediatrics (≥ 2 years): PNEUMOVAX® 23 is approved for use in children aged ≥ 2 years who are at increased risk for pneumococcal disease.

Pediatrics (0-2 years): PNEUMOVAX® 23 is not recommended for use in children below 2 years of age. Safety and effectiveness in children below the age of 2 years have not been established.

1.2 Geriatrics

PNEUMOVAX® 23 has been studied in the geriatric population (see 7.1 Special Populations, Geriatrics and 14 CLINICAL TRIALS).

2 CONTRAINDICATIONS

The use of PNEUMOVAX® 23 is contraindicated for patients with hypersensitivity to any component of the vaccine (see 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING).

4 DOSAGE AND ADMINISTRATION

4.2 Recommended Dose and Dosage Adjustment

The recommended dose of PNEUMOVAX® 23 is a single 0.5 mL injection given subcutaneously or intramuscularly (see 4.4 Administration).

Timing of Vaccination

Pneumococcal vaccine should be given at least two weeks before elective splenectomy, if possible.

For planning cancer chemotherapy or other immunosuppressive therapy (e.g., for patients with Hodgkin's disease or those who undergo organ or bone marrow transplantation), pneumococcal vaccination should be administered at least two weeks prior to the initiation of immunosuppressive therapy. Vaccination during chemotherapy or radiation therapy should be avoided. Based on literature reports, pneumococcal vaccine may be given as early as several months following completion of chemotherapy or radiation therapy for neoplastic disease. In Hodgkin's disease, immune response to vaccination may be impaired for two years or longer after intense chemotherapy (with or without radiation). During the two years following the completion of chemotherapy or other immunosuppressive therapy, antibody responses

improve in some patients as the interval between the end of treatment and pneumococcal vaccination increases.

Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis is confirmed.

Revaccination
Revaccination of immunocompetent persons previously vaccinated with 23-valent polysaccharide vaccine is not routinely recommended. However, revaccination once is recommended for persons ≥ 2 years of age who are at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least five years have passed since receipt of a first dose of pneumococcal vaccine.

The highest risk group includes persons with functional or anatomic asplenia (e.g., sickle cell disease or splenectomy), HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression (e.g., organ or bone marrow transplantation), and those receiving immunosuppressive chemotherapy (including long-term systemic corticosteroids) (see 1 INDICATIONS, 4.2 Recommended Dose and Dosage Adjustment, Timing of Vaccination).

If prior vaccination status is unknown for patients in the high risk group, patients should be given pneumococcal vaccine.

All persons ≥ 65 years of age who have not received vaccine within 5 years (and were < 65 years of age at the time of vaccination) should receive another dose of vaccine.

Because data are insufficient concerning the safety of pneumococcal vaccine when administered three or more times, revaccination following a second dose is not routinely recommended.

4.4 Administration

DO NOT INJECT INTRAVENOUSLY OR INTRADERMALLY.

Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit. PNEUMOVAX® 23 is a clear, colourless solution. The vaccine is used directly as supplied. No dilution or reconstitution is necessary. Phenol 0.25% has been added in the vaccine as a preservative.

Prefilled Syringe
The prefilled syringe is for single use only. Inject the entire contents of the syringe (0.5 mL) subcutaneously or intramuscularly (preferably in the deltoid muscle or lateral mid-thigh), with appropriate precautions to avoid intravascular administration.

5 OVERDOSAGE

There are no data with regard to overdosage.

For management of a suspected vaccine overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

To help ensure the traceability of vaccines for patient immunization record-keeping as well as safety monitoring, health professionals should record the time and date of administration, quantity of administered dose (if applicable), anatomical site and route of administration, brand name and generic name of the vaccine, the product lot number and expiry date.

Table 1 – Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Intramuscular or subcutaneous injection	Solution Each 0.5 mL dose contains 25 µg of capsular polysaccharide from each of 23 types of pneumococci: 1, 2, 3, 4, 5, 6B*, 7F, 8, 9N, 9V*, 10A, 11A, 12F, 14*, 15B, 17F, 18C, 19A*, 19F*, 20, 22F, 23F*, 33F *These serotypes most frequently cause drug-resistant pneumococcal infections	Sodium chloride Phenol Water for injection

Prefilled Syringe

PNEUMOVAX® 23 (pneumococcal vaccine, polyvalent, MSD Std.) is supplied as a sterile, clear, colourless liquid in a 1.5 mL glass syringe.

Inject the entire contents of the syringe (0.5 mL).

Composition: Each single dose (0.5 mL) contains:

Active Ingredients

Purified capsular polysaccharides from the following 23 serotypes of *Streptococcus pneumoniae* (Danish nomenclature):

1, 2, 3, 4, 5, 6B*, 7F, 8, 9N, 9V*, 10A, 11A, 12F, 14*, 15B, 17F, 18C, 19A*, 19F*, 20, 22F, 23F*, 33F

25 µg of each serotype

*These serotypes most frequently cause drug-resistant pneumococcal infections.

Other Ingredients

Excipients

Sodium chloride	0.9% (w/w)
Phenol	0.25% (w/w)
Water for injection	to volume

Packaging: Prefilled Syringe: PNEUMOVAX® 23 is supplied in 1.5 mL Type I glass barrel syringes with a round flange, rubber plunger stopper and plastic tip cap. Each syringe contains 0.5 mL dose of liquid vaccine.

The container closure systems of PNEUMOVAX® 23 are free of latex.

7 WARNINGS AND PRECAUTIONS

General

Epinephrine injection (1:1000) must be immediately available should an acute anaphylactoid reaction occur due to any component of the vaccine.

For planning cancer chemotherapy or other immunosuppressive therapy (e.g., for patients with Hodgkin's disease or those who undergo organ or bone marrow transplantation), the timing of the vaccination is critical (see 4.2 Recommended Dose and Dosage adjustment, Timing of Vaccination).

If the vaccine is administered to patients who are immunosuppressed due to either an underlying condition or medical treatment (e.g., immunosuppressive therapy such as cancer chemotherapy or radiation therapy), the expected serum antibody response may not be obtained and potential impairment of future immune responses to pneumococcal antigens may occur (see 4.2 Recommended Dose and Dosage adjustment, Timing of Vaccination).

Intradermal administration may cause severe local reactions.

Caution and appropriate care should be exercised in administering PNEUMOVAX® 23 (pneumococcal vaccine, polyvalent, MSD Std.) to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

Any febrile respiratory illness or other active infection is reason for delaying use of PNEUMOVAX® 23, except when, in the opinion of the physician, withholding the agent entails even greater risk.

In patients who require penicillin (or other antibiotic) prophylaxis against pneumococcal infection, such prophylaxis should not be discontinued after vaccination with PNEUMOVAX® 23.
PNEUMOVAX® 23 may not be effective in preventing pneumococcal meningitis in patients who have chronic cerebrospinal fluid (CSF) leakage resulting from congenital lesions, skull fractures, or neurosurgical procedures.

Routine revaccination of immunocompetent persons previously vaccinated with a 23-valent vaccine is not recommended. However, revaccination once is recommended for persons aged ≥ 2 years who are at highest risk for serious pneumococcal infections and those likely to have a rapid decline in pneumococcal antibody levels (see 4.2 Recommended Dose and Dosage adjustment, Revaccination).

As with any vaccine, vaccination with PNEUMOVAX® 23 may not result in complete protection in all recipients and lack of effect following PNEUMOVAX® 23 vaccination has been reported through post-market surveillance.

Reproductive Health: Female and Male Potential
PNEUMOVAX® 23 should be given to a pregnant woman only if clearly needed.

- **Fertility**

The possible effects of PNEUMOVAX® 23 for its potential to impair fertility are unknown.

- **Teratogenic Risk**

It is not known whether PNEUMOVAX® 23 can cause fetal harm when administered to a pregnant woman.

7.1 Special Populations

7.1.1 Pregnant Women
Animal reproduction studies have not been conducted with PNEUMOVAX® 23. It is also not known whether PNEUMOVAX® 23 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PNEUMOVAX® 23 should be given to a pregnant woman only if clearly needed.

7.1.2 Breast-feeding
It is not known whether this vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when PNEUMOVAX® 23 is administered to a nursing woman.

7.1.3 Pediatrics
PNEUMOVAX® 23 is not recommended for use in children less than 2 years of age. Safety and effectiveness in children below the age of 2 years have not been established. Children in this age group respond poorly to the capsular types contained in this vaccine (see 14 CLINICAL TRIALS, Immunogenicity).

7.1.4 Geriatrics
In one clinical trial of PNEUMOVAX 23, conducted post-licensure, a total of 629 subjects who were aged > 65 years and 201 subjects who were aged > 75 years were enrolled (see 8.2 Clinical Trial Adverse Reactions, 8.5 Post-Market Adverse Reactions, Geriatrics and 8 ADVERSE REACTIONS).

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview
The most common adverse reactions, reported in subjects vaccinated with PNEUMOVAX® 23 (pneumococcal vaccine, polyvalent, MSD Std.) for the first time in a clinical trial were: injection-site

pain/soreness (60.0%), injection-site swelling/induration (20.3%), injection-site erythema (16.4%), asthenia/fatigue (13.2%), myalgia (11.9%), and fever (1.4%). In post-marketing experience, warmth at the injection site, decreased limb mobility and peripheral edema in the injected extremity were reported. In addition, and rarely, cellulitis-like reactions of short onset time from vaccine administration were reported in post-marketing experience. Local reactions may be accompanied by systemic signs and symptoms including fever, leukocytosis and an increase in the laboratory value for serum C-reactive protein.

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials; therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

Persons 65 years of age or older were enrolled in several clinical studies of PNEUMOVAX® 23 that were conducted pre- and post-licensure. In the largest of these studies, the safety of PNEUMOVAX® 23 in adults 65 years of age and older (n=629; median age of 72 years) was compared to the safety of PNEUMOVAX® 23 in adults 50 to 64 years of age (n=379; median age of 58 years). All subjects in this study were ambulatory and had an expected prevalence of age associated chronic diseases. The clinical data did not suggest an increased rate or severity of adverse reactions among subjects ≥ 65 years of age compared to those 50 to 64 years of age. However, since elderly individuals may not tolerate medical interventions as well as younger individuals, a higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out.

In a clinical trial, an increased rate of self-limited local reactions has been observed with revaccination at 3–5 years following primary vaccination. It was reported that the overall injection-site adverse experiences rate for subjects ≥ 65 years of age was higher following revaccination (79.3%) than following primary vaccination (52.9%). The reported overall injection-site adverse experiences rate for re-vaccinees and primary vaccinees who were 50 to 64 years of age were similar (79.6% and 72.8% respectively). In both age groups, re-vaccinees reported a higher rate of a composite endpoint (any of the following: moderate pain, severe pain, and/or large induration at the injection site) than primary vaccinees. Among subjects ≥ 65 years of age, the composite endpoint was reported by 30.6% and 10.4% of revaccination and primary vaccination subjects, respectively, while among subjects 50–64 years of age, the endpoint was reported by 35.5% and 18.9% respectively. The injection site reactions occurred within the 3-day monitoring period and typically resolved by day 5. The rate of overall systemic adverse experiences was similar among both primary vaccinees and re-vaccinees within each age group. The most common systemic adverse experiences were asthenia/fatigue, myalgia and headache. Among subjects ≥ 65 years of age, asthenia/fatigue and myalgia were reported more frequently following revaccination than primary vaccination. The observed generally small increase (≤ 13%) in post-vaccination use of analgesics returned to baseline by day 5.

Other Adverse Experiences reported in Clinical Trials and/or in Post-Marketing Experience include:

Body as a Whole

Cellulitis

Asthenia

Fever

Chills

Malaise

Digestive System

Nausea

Vomiting

Hematologic/Lymphatic System

Lymphadenitis

Lymphadenopathy

Thrombocytopenia in patients with stabilized idiopathic thrombocytopenic purpura

Hemolytic anemia in patients who have had other hematologic disorders

Leukocytosis

Hypersensitivity reactions including:

Anaphylactoid reactions

Serum sickness

Angioneurotic edema

Musculoskeletal System

Arthralgia

Arthritis

Myalgia

Nervous System

Headache

Paresthesia

Radiculoneuropathy

Guillain-Barré Syndrome

Febrile convulsion

Skin

Rash

Urticaria

Erythema multiforme

8.2.1 Clinical Trial Adverse Reactions – Pediatrics

A clinical study was conducted to evaluate the safety and immunogenicity of Pneumococcal polysaccharide vaccine in 102 individuals, including 25 subjects 2 to 17 years of age, 27 subjects 18 to 49 years of age, and 50 subjects 50 years of age and older. The type and severity of injection-site and systemic adverse reactions reported among children 2 to 17 years of age were comparable to those reported among adults 18 years of age and older. However, the proportions of subjects reporting injection-site and system adverse reactions were higher among subjects 2 to 17 years of age than those 18 years of age and older.

8.5 Post-Market Adverse Reactions

Geriatrics:

Post-marketing reports have been received in which some frail elderly individuals with multiple co-morbid conditions had severe adverse experiences and a complicated clinical course following vaccination.

9 DRUG INTERACTIONS

9.4 Drug-Drug Interactions

Use with Other Vaccines

It is recommended that pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection in the other arm) without an increase in side effects or decreased antibody response to either vaccine.

In contrast to pneumococcal vaccine, influenza vaccine is recommended annually, for appropriate populations.

PNEUMOVAX® 23 and ZOSTAVAX® (zoster vaccine live, attenuated [Oka/Merck]) should not be given concurrently because concomitant use in a clinical trial resulted in reduced immunogenicity of ZOSTAVAX®. In this trial, the immunogenicity of PNEUMOVAX® 23 was not affected by ZOSTAVAX®. Consider administration of the two vaccines separated by at least 4 weeks.

10 CLINICAL PHARMACOLOGY

10.1 Mechanism of Action

PNEUMOVAX® 23 (pneumococcal vaccine, polyvalent, MSD Std.) induces type-specific antibodies that enhance opsonization, phagocytosis, and killing of pneumococci by leukocytes and other phagocytic cells. The levels of antibodies that correlated with protection against pneumococcal disease have not been clearly defined.

10.3 Pharmacokinetics

Duration of Effect

Following pneumococcal vaccination, serotype-specific antibody levels decline after 5–10 years. A more rapid decline in antibody levels may occur in some groups (e.g., children). Limited published data suggest that antibody levels may decline more rapidly in the elderly > 60 years of age (see 4.2 Recommended Dose and Dosage Adjustment Revaccination).

11 STORAGE, STABILITY AND DISPOSAL

Store unopened and opened pre-filled syringes at 2°C – 8°C. All vaccines must be discarded after the expiration date.

PNEUMOVAX® 23 should be administered as soon as possible after being removed from the refrigerator. Vaccine should be discarded if not administered after removal from the refrigerator.
In the event of temporary high temperature excursions, stability data indicate that PNEUMOVAX® 23 is stable at temperatures up to 25°C for 24 hours.

12 SPECIAL HANDLING INSTRUCTIONS

Any unused vaccine or waste material should be disposed in accordance with local requirements.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

Drug Substance

Proper name: Pneumococcal vaccine, polyvalent, MSD Std.

Product Characteristics:

PNEUMOVAX® 23 (pneumococcal vaccine, polyvalent, MSD Std.) is a sterile, liquid vaccine for intramuscular or subcutaneous injection. It consists of a mixture of highly purified capsular polysaccharides from the 23 most prevalent or invasive pneumococcal types of *Streptococcus pneumoniae*, including the six serotypes that most frequently cause invasive drug-resistant pneumococcal infections among children and adults including the eight serotypes that most frequently cause invasive drug-resistant pneumococcal types of Streptococcus pneumoniae in Canada between 2011 and 2020 (see Table 2).

Table 2: 23 Pneumococcal Capsular Types Included in PNEUMOVAX® 23

Pneumococcal Types (Danish Nomenclature)
1 3* 4 5 6B 7F* 8* 9N 9V* 10A 11A 12F 14* 15B* 17F 18C 19A* 19F* 20 22F 23F 33F

*These serotypes most frequently cause drug-resistant pneumococcal infections

PNEUMOVAX® 23 is manufactured according to methods developed by Merck Research Laboratories. Each 0.5 mL dose of vaccine contains 25 µg of each polysaccharide type dissolved in isotonic saline solution containing 0.25% phenol as a preservative.

14 CLINICAL TRIALS

14.1 Clinical Trials by Indication

Table 3- Summary of patient demographics for clinical trials

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex

315	Randomized, single dose, with active (meningococcal vaccine) and placebo controls	Group 1: Pneumococcal polysaccharide 6-valent vaccine, Danish types 1, 2, 4, 8, 12F, and 25; 300 µg/0.5 mL (50 µg/type) subcutaneous injection. Group 2: Meningococcal polysaccharide vaccine, Group A, 50 µg/0.5 mL subcutaneous injection. Group 3: Placebo (saline) 0.5 mL subcutaneous injection.	Group 1: 983 Group 2: 1051 Group 3: 985	18 to 45 years 17 to 53 years 16 to 44 years	Male
315A	Randomized, single dose, with active (meningococcal vaccine) and placebo controls	Group 1: Pneumococcal polysaccharide 12-valent vaccine, Danish types 1, 2, 3, 4, 6A, 8, 9N, 12F, 25, 7F, 18C, and 46, 600 µg/0.5 mL (50 µg per type) subcutaneous injection. Group 2: Meningococcal polysaccharide bivalent vaccine, groups A and C, 100 µg/0.5 mL (50 µg per group) subcutaneous injection. Group 3: Placebo (saline) 0.5mL subcutaneous injection.	Group 1: 718 Group 2: 775 Group 3: 718	17 to 51 years 17 to 55 years 17 to 58 years	Male

331	Randomized, single dose, placebo controlled	Pneumococcal polysaccharide 14-valent vaccine, Danish types 1, 2, 3, 4, 5, 6A, 8, 12F, 14, 23F, 25, 7F, 18C, and 46; 0.5 mL (93 ug/serotype/mL). Saline placebo, 0.5 mL. Route of administration not specified.	12,755	Not specified	Not specified
378	Randomized, single dose, (optional second dose at 6 months) with placebo control	Pneumococcal polysaccharide 12-valent vaccine, Danish types 1, 3, 4, 6A, 8, 9N, 12F, 14, 19F, 23F, 7F, 18C. 300 µg/0.25 mL (25 µg/type). Saline placebo, 0.25-mL dose. Route of administration not specified.	9730 (4994 pneumococcal vaccine and 4736 placebo)	2 to 48 months	Not specified

14.2 Study Results

Efficacy

The protective efficacy of pneumococcal vaccines containing 6 or 12 capsular polysaccharides was investigated in two controlled studies of young, healthy gold miners in South Africa, in whom there was a high attack rate for pneumococcal pneumonia and bacteremia. Capsular type-specific attack rates for pneumococcal pneumonia were observed for the period from 2 weeks through about 1 year after vaccination. Protective efficacy was 76% and 92%, respectively, in the two studies for the capsular types represented.

In similar studies carried out by Dr. R. Austrian and associates, using similar pneumococcal vaccines prepared for the National Institutes of Allergy and Infectious Diseases, the reduction in pneumonia caused by the capsular types contained in the vaccines was 79%. Reduction in type-specific pneumococcal bacteremia was 82%.

A prospective study in France found pneumococcal vaccine to be 77% effective in reducing the incidence of pneumonia among nursing home residents.

In the United States, two post licensure randomized controlled trials, in the elderly or patients with chronic medical conditions, who received a multivalent polysaccharide vaccine, did not support the efficacy of the vaccine for nonbacteremic pneumonia. However, these studies may have lacked sufficient statistical power to detect a difference in the incidence of laboratory-confirmed, nonbacteremic pneumococcal pneumonia between the vaccinated and nonvaccinated study groups.

A meta-analysis of nine randomized controlled trials of pneumococcal vaccine concluded that pneumococcal vaccine is efficacious in reducing the frequency of nonbacteremic pneumococcal pneumonia among adults in low-risk groups but not in high-risk groups. These studies may have been limited because of the lack of specific and sensitive diagnostic tests for nonbacteremic pneumococcal pneumonia. The pneumococcal polysaccharide vaccine is not effective for the prevention of acute otitis media and common upper respiratory diseases (e.g., sinusitis) in children.

More recently, multiple, case-control studies have shown pneumococcal vaccine is effective in the prevention of serious pneumococcal disease, with point estimates of efficacy ranging from 56% to 81% in immunocompetent persons.

Only one case-control study did not document effectiveness against bacteremic disease possibly due to study limitations, including small sample size and incomplete ascertainment of vaccination status in patients. In addition, case-patients and persons who served as controls may not have been comparable regarding the severity of their underlying medical conditions, potentially creating a biased underestimate of vaccine effectiveness.

A serotype prevalence study, based on the Centers for Disease Control pneumococcal surveillance system, demonstrated 57% overall protective effectiveness against invasive infections caused by serotypes included in the vaccine in persons ≥ 6 years of age, 65–84% effectiveness among specific patient groups (e.g., persons with diabetes mellitus, coronary vascular disease, congestive heart failure, chronic pulmonary disease, and anatomic asplenia) and 75% effectiveness in immunocompetent persons aged ≥ 65 years of age. Vaccine effectiveness could not be confirmed for certain groups of immunocompromised patients; however, the study could not recruit sufficient numbers of unvaccinated patients from each disease group.

In an earlier study, vaccinated children and young adults aged 2 to 25 years who had sickle cell disease, congenital asplenia, or undergone a splenectomy experienced significantly less bacteremic pneumococcal disease than patients who were not vaccinated.

14.3 Immunogenicity

It has been established that the purified pneumococcal capsular polysaccharides induce antibody production and that such antibody is effective in preventing pneumococcal disease. Clinical studies have demonstrated the immunogenicity of each of the 23 capsular types when tested in polyvalent vaccines.

Studies with 12-, 14-, and 23-valent pneumococcal vaccines in children two years of age and older and in adults of all ages showed immunogenic responses. Protective capsular type-specific antibody levels generally develop by the third week following vaccination.

Bacterial capsular polysaccharides induce antibodies primarily by T-cell-independent mechanisms. Therefore, antibody response to most pneumococcal capsular types is generally poor or inconsistent in children aged < 2 years whose immune systems are immature.

Immunogenicity following concomitant administration

In a double-blind, controlled clinical trial, 473 adults, 60 years of age or older, were randomized to receive ZOSTAVAX® and PNEUMOVAX® 23 concomitantly (N=237), or PNEUMOVAX® 23 alone followed 4 weeks later by ZOSTAVAX® alone (N=236). At four weeks postvaccination, the VZV antibody levels following concomitant use were significantly lower than the VZV antibody levels following nonconcomitant administration (GMTs of 338 vs. 484 gpELISA units/mL, respectively; GMT ratio = 0.70

(95% CI: [0.61, 0.80])). VZV antibody levels 4 weeks postvaccination were increased 1.9-fold (95% CI: [1.7, 2.1]; meeting the pre-specified acceptance criterion) in the concomitant group vs. 3.1-fold (95% CI: [2.8, 3.5]) in the nonconcomitant group. The GMTs for PNEUMOVAX® 23 antigens were comparable between the two groups. Concomitant use of ZOSTAVAX® and PNEUMOVAX® 23 demonstrated a safety profile that was generally similar to that of the two vaccines administered nonconcomitantly.

15 MICROBIOLOGY

No microbiological information is required for this drug product.

16 NON-CLINICAL TOXICOLOGY

Carcinogenicity: PNEUMOVAX® 23 has not been evaluated for the potential to cause carcinogenicity.

Genotoxicity: PNEUMOVAX® 23 has not been evaluated for the potential to cause genotoxicity.

Reproductive and Developmental Toxicology: PNEUMOVAX® 23 has not been evaluated for the potential to cause reproductive and developmental toxicity.

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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