Pneumococcal Polysaccharide Vaccine Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.290**
Created by:	Province-wide Immunization Program Standards and Quality		
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	PNEUMOVAX® 23
Manufacturer	Merck Canada Inc.
Biological Classification	Inactivated: Polysaccharide
Indications for Provincially Funded Vaccine	**Routine Recommended Immunization** • Persons 65 years of age or older. • All residents of long-term care facilities **Note:** All individuals should receive one dose of pneumococcal polysaccharide vaccine at 65 years of age and older, (as long as 5 years have passed since a previous dose of this vaccine), regardless of the number of doses received prior to 65 years of age. **Medically at Risk** • **Persons 24 months of age up to and including 64 years of age with the following:** o Alcoholism. o Asplenia/hyposplenism (functional or anatomic). o Chronic cardiac disease. o Chronic cerebral spinal fluid (CSF) leak. o Chronic liver disease, including hepatic cirrhosis due to any cause, hepatitis B carriers and hepatitis C infection. o Chronic neurologic conditions that may impair clearance of oral secretions. o Chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids). o Chronic renal disease, including nephrotic syndrome. o Cochlear implants (candidates and recipients). o Congenital immune deficiencies involving any part of the immune system, including B-lymphocyte (humoral) immunity; T-lymphocyte (cell) mediated immunity; complement system (properdin or factor D deficiencies); or phagocytic functions. o Diabetes mellitus. o Hematopoietic stem cell transplant (HSCT) recipients. See: Standard for Immunization of Transplant Candidates or Recipients #08.304. o HIV infection. o Undergoing or anticipating immunosuppressive therapy including: ▪ use of long term corticosteroids, ▪ chemotherapy, ▪ radiation therapy, ▪ post-organ transplant therapy,

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	▪ Biologic and non-biologic immunosuppressive therapies for: ▪ inflammatory arthropathies, e.g. systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis, ▪ inflammatory dermatological conditions, e.g. psoriasis, severe atopic dermatitis and eczema, and ▪ inflammatory bowel disease, e.g. Crohn's disease, ulcerative colitis. ▪ For additional information see: Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression #08.305. **Notes:** Individuals prescribed eculizumab (Soliris®) are at increased risk of serious infections, especially with encapsulated bacteria, such as *Streptococcus pneumonia,* therefore, they should receive pneumococcal polysaccharide vaccine at least eight weeks after receiving Prevnar® 13. See the Pneumococcal Polysaccharide Vaccine #07.290 and Pneumococcal Conjugate #07.291 Vaccine Biological Pages regarding scheduling for spacing between products. • Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma, Hodgkin's disease and non-Hodgkin's lymphomas, and multiple myeloma. • Malignant solid organ tumors either currently or within past 5 years. • Living in homeless/chronically disadvantaged situations: o Definition: At the time of diagnosis, the individual did not have an address or home (apartment, townhouse, etc.). This would include people staying in shelter, cars, etc. o Document "No Fixed Address" under home address. If the individual is using a friend/relative's mailing address, it can be included in brackets. • Sickle cell disease and other hemoglobinopathies. • Solid organ or islet transplant (SOT) candidates and recipients o See: Standard for Immunization of Transplant Candidates or Recipients #08.304. • Illicit injection drug use. **Notes:** • Pneumococcal conjugate vaccine may also be recommended for individuals at highest risk of IPD. See Biological Products: Pneumococcal 13-valent Conjugate Vaccine for these risk groups. • Individuals 18 years of age and older, including those with conditions that place them at higher risk for IPD, who have received 20-valent pneumococcal conjugate vaccine (PCV 20), according to the schedule(s) outlined in the product monograph, are not recommended to receive Pneumo-P at this time. • Having received a dose of 20-valent pneumococcal conjugate vaccine (PCV 20) can be considered sufficient for individuals recommended Pneumo-P or Pneumo-P in combination with PCV13. Post-exposure Previous IPD does not confer immunity or preclude immunization with pneumococcal vaccine.
Preferred Use	N/A
Dose	0.5 mL
Route	I.M. or S.C.

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	• Past experience has shown that there are fewer local reactions following IM administration of this vaccine.

Schedule	**One dose is sufficient for most individuals.**
	• If possible, vaccine should be given at least 14 days prior to splenectomy or initiation of immunosuppressive therapy.
	• If vaccine cannot be administered before initiation of immunosuppressive therapy, generally a period of at least 3 months should elapse between therapy cessation and the vaccine.
	  ○ If immunosuppressive therapy will be long term/ongoing and/or for those with malignant hematological disorders, currently undergoing immunosuppressive therapy the vaccine should be administered as soon as possible.
	
	Re-immunization:
	A **one-time** reinforcing dose of pneumococcal polysaccharide vaccine should be offered 5 years later and is recommended ONLY for those individuals at highest risk of invasive pneumococcal disease. This includes people with:
	• Asplenia/hyposplenism (functional or anatomic).
	• Chronic renal failure or nephrotic syndrome.
	• Chronic liver disease including hepatic cirrhosis.
	• Congenital immunodeficiencies involving any part of the immune system.
	• HIV infection.
	• HSCT recipients may be an exception to this recommendation – see: Standard for Immunization of Transplant Candidates or Recipients #08.304
	• Undergoing or anticipating immunosuppression related to therapy including:
	  ○ use of long term corticosteroids,
	  ○ chemotherapy
	  ○ radiation therapy
	  ○ post-organ transplant therapy,
	  ○ biologic and non-biologic immunosuppressive therapies (e.g. Soliris® medication) for:
	  ▪ inflammatory arthropathies, e.g. systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,
	  ▪ inflammatory dermatological conditions, e.g., psoriasis, severe atopic dermatitis and eczema, and
	  ▪ inflammatory bowel disease, e.g., Crohn's disease, ulcerative colitis.
	• Malignant hematological disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma Hodgkin's disease and non-Hodgkin's lymphoma and multiple myeloma
	• Sickle cell disease
	• SOT candidates and recipients. Standard for Immunization of Transplant Candidates or Recipients or Recipients #08.304
	Notes:
	Individuals with underlying medical conditions would be eligible for a dose after turning 65 years of age – as long as 5 years have passed since a previous Pneumo-P, regardless of their prior immunization history.
	Pneumococcal conjugate vaccine may also be recommended for individuals at highest risk for IPD. See #07,291 Pneumococcal Conjugate Vaccine Biological Page.

Contraindications/ Precautions	**Contraindications:** • Persons less than 2 years of age. • Known severe hypersensitivity to any component of the vaccine. • Anaphylactic or other allergic reaction to previous dose of vaccine containing similar components.

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	Precautions: • Defer immunization in persons with severe acute febrile illness. • If antibiotics for prophylaxis against pneumococcoal infection are required they should not be discontinued after immunization with Pneumovax®23.
Possible Reactions	**Common:** • injection site pain, redness, warmth, swelling and local induration • fever (less than 38.8°C) • asthenia, fatigue • myalgia • headache **Rare:** • chills, malaise • nausea, vomiting • lymphadenitis, lymphadenopathy • rash, urticarial • arthralgia and paresthesia, • fever, and afebrile and febrile seizures • cellulitis-like reaction • allergic reactions, anaphylaxis • as with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.
Pregnancy	Can be administered to eligible pregnant women.
Lactation	Can be administered to eligible breastfeeding women.
Composition	Each 0.5 mL dose contains: • 25 mcg of each of the *Streptococcus pneumoniae serotypes:* 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, 33F (Danish nomenclature) • sodium chloride • phenol • water for injection
Blood/Blood Products	Contains no human blood/blood products
Bovine/Porcine Products	• Contains no bovine products; however, bovine proteins and other macromolecular components are used in the manufacturing process (culture media) • Contains no porcine products
Latex	There is no latex in the vaccine or vaccine the packaging.
Interchangeability	The current available pneumococcal polysaccharide vaccines are generically equivalent. U.S. and Danish systems assign different nomenclature to the serotypes so that although they look different in a list, the included strains are actually the same.
Administration with Other Products	• If both pneumococcal polysaccharide and pneumococcal conjugate vaccines are indicated, it is recommended that the conjugate vaccine series/dose be completed/given prior to administering the polysaccharide vaccine with a minimum of eight weeks between the two vaccines. • If pneumococcal polysaccharide vaccine has already been administered, there must be an interval between does as specified below: ○ Children 2 years up to and including 17 years of age: pneumococcal conjugate vaccine may be administered with a minimal interval of at least eight weeks after the pneumococcal polysaccharide vaccine.

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	○ Adults 18 years of age and older – pneumococcal conjugate vaccine may be administered with a minimal interval of at least one year after the pneumococcal polysaccharide vaccine ○ **The exception to this is HSCT recipients.** Refer to Standard for Immunization of Transplant Candidates and Recipients #08.304. • Can be given at the same time as other inactivated and live vaccines using a separate needle and syringe for each vaccine. The same limb may be used if necessary, but different sites on the limb must be chosen. • Contrary to product monograph information, the Canadian Immunization Guide (Evergreen Edition) advises that PNEUMOVAX® 23 vaccine may be administered concomitantly with ZOSTAVAX®. Although one study showed slightly lower antibody titres when ZOSTAVAX® vaccine was given simultaneously with Pneumococcal 23-valent polysaccharide vaccine, its clinical significance is unclear. There is a benefit to giving the two vaccines concomitantly and not risking a lost opportunity to give vaccine to someone who may not return for follow up.
Appearance	Clear, colorless liquid
Storage	• Store at +2^{0}C to +8^{0}C. • Do not freeze. • Do not use beyond the labeled expiry date. • Store in original packaging when possible to protect from light.
Vaccine Code	PNEUMO-P
Antigen Code	PNEUMO-P
Licensed for	Routine immunization for individuals 50 years of age or older. Individuals 24 months of age and older with specific medical conditions identified under Indications.

Notes:

- There is no deferral for blood donation required after pneumococcal immunization. Refer to Canadian Blood Services for more information.

Program Notes:

- 1997 April – Pneumovax®23 and Pneumo 23® Pneumococcal polysaccharide vaccine introduced into program for high-risk groups except 65 years of age and older. End date for Pneumo 23® 2008-09.
- 1998 Fall – Pneumococcal polysaccharide vaccine for individuals 65 years of age and older.
- 2014 October – Illicit drug use added to indications.
- 2015 February 10 – Expanded indication for immunosuppressive therapy regarding medication Solaris®
- 2019 January 1 – Vaccine becomes available at pharmacies for healthy individuals age 65 years of age and older.
- 2022 December 9 – Updated recommendation for adults who privately purchase 20-valent pneumococcal conjugate vaccine.

Related Resources:

- Alberta Health Services Website (2018). Pneumococcal Polysaccharide Vaccine Package http://www.albertahealthservices.ca/2824.asp

References:

1. Alberta Health, Health System Accountability and Performance Division, Alberta Immunization Policy. Biological Products (2022 December 9). Pneumococcal Vaccine, 23-valent Polysaccharide (Pneumo-P):
2. Merck Canada Inc. (2016, April 15). PNEUMOVAX®23: Pneumococcal vaccine polyvalent, MSD std.. *Product monograph.*
3. National Advisory Committee on Immunization. (2015). *Canadian Immunization Guide (Evergreen Edition).* Ottawa, ON: Public Health Agency of Canada. http://www.phac-aspc.gc.ca/publicat/cig-gci/