## Section 7: Biological Product Information

**Standard #:** 07.290

**Created by:** Province-wide Immunization Program Standards and Quality

**Approved by:** Province-wide Immunization Program, Standards and Quality

**Approval Date:** September 27, 2011  **Revised:** March 1, 2023

### PNEUMOVAX® 23

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Merck Canada Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Classification</td>
<td>Inactivated: Polysaccharide</td>
</tr>
</tbody>
</table>

### 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:
  - Alcoholism.
  - Asplenia/hyposplenism (functional or anatomic).
  - Chronic cardiac disease.
  - Chronic cerebral spinal fluid (CSF) leak.
  - Chronic liver disease, including hepatic cirrhosis due to any cause, hepatitis B carriers and hepatitis C infection.
  - Chronic neurologic conditions that may impair clearance of oral secretions.
  - Chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).
  - Chronic renal disease, including nephrotic syndrome.
  - Cochlear implants (candidates and recipients).
  - 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.
  - Diabetes mellitus.
  - Hematopoietic stem cell transplant (HSCT) recipients. See: Standard for Immunization of Transplant Candidates or Recipients #08.304.
  - HIV infection.
  - Undergoing or anticipating immunosuppressive therapy including:
    - use of long term corticosteroids,
    - chemotherapy,
    - radiation therapy,
    - post-organ transplant therapy,
| **PNEUMOVAX® 23** | 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:  
  - 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.  
  - 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  
  - 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. |
### 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 #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

<table>
<thead>
<tr>
<th>Contraindications/Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contraindications:</strong></td>
</tr>
<tr>
<td>• Persons less than 2 years of age.</td>
</tr>
<tr>
<td>• Known severe hypersensitivity to any component of the vaccine.</td>
</tr>
<tr>
<td>• Anaphylactic or other allergic reaction to previous dose of vaccine containing similar components.</td>
</tr>
</tbody>
</table>
**PNEUMOVAX® 23**

**Precautions:**
- Defer immunization in persons with severe acute febrile illness.
- If antibiotics for prophylaxis against pneumococcal infection are required they should not be discontinued after immunization with Pneumovax®23.
- Fever and shivering were more frequent when Pneumovax® 23 vaccine was co-administered with Shingrix® vaccine.

**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:
PNEUMOVAX® 23

- 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.
- 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°C to +8°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.
- 2023 March 1 – Updated precautions to include co-administration of Shingrix® vaccine.

**Related Resources:**

**References:**
<table>
<thead>
<tr>
<th>No.</th>
<th>Reference</th>
</tr>
</thead>
</table>