Pneumococcal Vaccine, 23-valent Polysaccharide: PNEUMOVAX® 23

Revision Date: August 10, 2015

Please consult the Product Monograph\(^1\) for further information about the vaccine.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Merck Canada Inc.</th>
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</thead>
<tbody>
<tr>
<td>Off license use</td>
<td>None</td>
</tr>
<tr>
<td>Indications for use of provincially funded vaccine</td>
<td>Pneumococcal conjugate vaccine may also be recommended for individuals at highest risk of invasive pneumococcal disease (IPD). See Biological Products: Pneumococcal 13-valent Conjugate Vaccine for these risk groups.</td>
</tr>
</tbody>
</table>
|                     | - All individuals 65 years of age and older.\(^2\)  
                     |   \textbf{Note:} All individuals should receive one dose of Pneu-P-23 after they turn 65 years of age – as long as 5 years have passed since a previous Pneu-P-23, regardless of their prior immunization history.\(^2\)  
                     | - All residents of long-term facilities\(^3\)  
                     | - All individuals 2 years of age and older with:  
                     |   - 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.\(^2\)  
                     |   - Chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).\(^4\)  
                     |   - 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.\(^3\)  
                     |   - Diabetes mellitus.  
                     |   - Hematopoietic stem cell transplant (HSCT) recipients. See Immunization for Child Hematopoietic Stem Cell Transplant Recipients and Immunization for Immunization for Adult Hematopoietic Stem Cell Transplant Recipients.  
                     |   - HIV infection.  
                     |   - Immunosuppressive therapy including use of long term corticosteroids, chemotherapy, radiation therapy, post-organ transplant therapy, and certain anti-rheumatic drugs.\(^3\)  
                     |   \textbf{Note:} Individuals prescribed eculizumab (Soliris®) are at increased risk of serious infections, especially with encapsulated bacteria, such as \textit{Streptococcus pneumoniae};\(^5\) therefore, they should receive pneumococcal polysaccharide vaccine at least eight weeks after receiving Prevnar® 13. See scheduling for further spacing information.  
                     |   - Malignant neoplasms including leukemia, Hodgkin’s and non- Hodgkin’s  
                     |   - Immunocompromised patients (e.g., children with acute lymphoblastic leukemia) and those with severe malnutrition.  
                     |   - Patients with chronic neurologic conditions that may impair clearance of oral secretions.  
                     |   - Patients with chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).  
                     |   - Patients with chronic renal disease, including nephrotic syndrome.  
                     |   - Recipients of bone or joint procedures.  
                     |   - Recipients of cochlear implants (candidates and recipients).  
                     |   - Recipients of hematopoietic stem cell transplantation (HSCT).  
                     |   - Recipients of immunosuppressive therapy including use of long term corticosteroids, chemotherapy, radiation therapy, post-organ transplant therapy, and certain anti-rheumatic drugs.\(^3\)  
                     |   - Recipients of immunocompromised patients (e.g., children with acute lymphoblastic leukemia) and those with severe malnutrition.  
                     |   - Recipients of immunocompromised patients with chronic neurologic conditions that may impair clearance of oral secretions.  
                     |   - Recipients of immunocompromised patients with chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).  
                     |   - Recipients of immunocompromised patients with chronic renal disease, including nephrotic syndrome.  
                     |   - Recipients of immunocompromised patients with chronic neurologic conditions that may impair clearance of oral secretions.  
                     |   - Recipients of immunocompromised patients with chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).  
                     |   - Recipients of immunocompromised patients with chronic renal disease, including nephrotic syndrome.  
                     |   - Recipients of immunocompromised patients with chronic neurologic conditions that may impair clearance of oral secretions.  
                     |   - Individuals with a high risk of invasive pneumococcal disease (IPD). See Biological Products: Pneumococcal 13-valent Conjugate Vaccine for these risk groups.  
                     |   - High-risk individuals with chronic renal disease, including nephrotic syndrome.  
                     |   - Individuals with IgA deficiency.  
                     |   - Individuals with chronic neurologic conditions that may impair clearance of oral secretions.  
                     |   - Individuals with chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).  
                     |   - Individuals with chronic renal disease, including nephrotic syndrome.  
                     |   - Individuals with immunocompromised patients (e.g., children with acute lymphoblastic leukemia) and those with severe malnutrition.  
                     |   - Individuals with immunocompromised patients with chronic neurologic conditions that may impair clearance of oral secretions.  
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                     |   - Individuals with immunocompromised patients with chronic neurologic conditions that may impair clearance of oral secre
lymphomas, multiple myeloma and other malignancies.

- 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 shelters, 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 under home address.
- Sickle cell disease and other hemoglobinopathies.³
- Solid organ or islet transplant (SOT) candidates and recipients
  See Immunization for Children Expecting Solid Organ Transplant at 18 Months of Age or Older (Catch-up Schedule) and Immunization for Adult Solid Organ Transplant Candidates and Recipients.
- Illicit injection drug use

**Post-exposure**

Previous IPD does not confer immunity or preclude immunization with pneumococcal vaccine.

For disease investigation and reporting requirements refer to Public Health Notifiable Disease Management Guidelines – Invasive Pneumococcal Disease.⁶

| Use in children younger than two years of age | Not recommended for children younger than two years of age due to inadequate immune response. |
| Dose | 0.5 mL |
| Route | Intramuscular or subcutaneous injection |
| Schedule | One dose for most individuals |
  | **Notes:** |
  | • If possible, vaccine should be administered at least 14 days before splenectomy or initiation of immunosuppressive therapy.³ |
  | • When both pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine are indicated, the pneumococcal conjugate vaccine should be administered first with a minimum interval of at least eight weeks between the two vaccines. However, if pneumococcal polysaccharide vaccine has already been administered, there must be an interval between doses as specified below: |
  | - Children 2 – 17 years of age: pneumococcal conjugate vaccine may be administered with a minimal interval of at least eight weeks after the pneumococcal polysaccharide vaccine.⁷,⁸ |
  | - 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.⁹,¹⁰ |
  | **Reinforcing dose:** |
  | - A one-time reinforcing dose should be offered 5 years later to those who have:²,³ |
  |   - Asplenia/hyposplenism (functional or anatomic) or sickle cell disease |
  |   - Chronic renal failure or nephrotic syndrome |
  |   - Hepatic cirrhosis |
  |   - HIV infection |
Alberta Health, Public Health and Compliance Division  
Alberta Immunization Policy - Biological Products  
Pneumococcal Polysaccharide *PNEUMOVAX® 23*  

August 10, 2015

- HSCT recipients may be an exception to this recommendation – see [Immunization for Child Hematopoietic Stem Cell Transplant Recipients](#) and [Immunization for Adult Hematopoietic Stem Cell Transplant Recipients](#).
- Immunosuppression related to disease or therapy (e.g., lymphoma, Hodgkin’s disease, multiple myeloma, high-dose systemic steroids, Soliris® medication)
- Sickle cell disease
- SOT candidates and recipients – see [Immunization for Children Expecting Solid Organ Transplant at 18 Months of Age or Older (Catch-up Schedule)](#) and [Immunization for Adult Solid Organ Transplant Candidates and Recipients](#).

**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 Pneu-P-23, regardless of their prior immunization history (maximum of 3 doses of Pneu-P-23 in a lifetime).²

Pneumococcal conjugate vaccine may also be recommended for individuals at highest risk of IPD. See [Pneumococcal 13-valent Conjugate Vaccine: Prevnar® 13](#) for risk groups.

### Contraindications

- Known severe hypersensitivity to any component of PNEUMOVAX® 23.
- Anaphylactic or other allergic reaction to a previous dose of vaccine containing pneumococcal antigen

### Precautions

- PNEUMOVAX® 23 will only protect against serotypes of *S. pneumoniae* that are contained in the vaccine. It will not protect against other micro-organisms that cause invasive infection, otitis media and pneumonia.¹
- If antibiotics for prophylaxis against pneumococcal infection are required, these should not be discontinued after immunization with PNEUMOVAX® 23.¹¹
- Pneumococcal vaccine should be given at least 14 days prior to initiation of immunosuppressive therapy (cancer chemotherapy and other immunosuppressive therapies)¹³ when possible.

### Possible reactions

#### Local reactions:

- Soreness, erythema, swelling, local induration, decreased limb mobility and peripheral edema in the injected limb.¹³
- Rarely, cellulitis-like reactions have been reported.¹³

#### Systemic reactions:

- Fever, rash, arthralgia, arthritis, chills, nausea, vomiting, lymphadenitis, lymphadenopathy, headache, malaise, myalgia, asthenia, urticaria, hemolytic anemia (in patients who have had other hematologic disorders), anaphylactoid reactions, serum sickness, angioneurotic edema, paresthesia, leukocytosis, radiculoneuropathy, Guillain-Barré syndrome (GBS), febrile convulsion, erythema multiforme and thrombocytopenia in patients with stabilized idiopathic thrombocytopenic purpura have been reported.¹³

**Notes:**

- Re-immunization of healthy adults less than two years after the initial dose is associated with increased local and systemic reactions.³
- Re-immunization after intervals of 3 – 5 years may be associated with higher adverse events particularly, pain and/or induration at the injection site.¹⁹
• Individuals who have had pneumococcal infections prior to vaccine administration may have increased reactions to pneumococcal vaccine usually localized to the injection site but may be systemic.\textsuperscript{11}

Refer to: Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.\textsuperscript{12}

<table>
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<tr>
<th>Pregnancy</th>
<th>Pregnant women with conditions that are a risk for IPD should receive pneumococcal vaccine as indicated.\textsuperscript{3}</th>
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<td>Lactation</td>
<td>Breastfeeding women with conditions that are a risk for IPD should receive pneumococcal vaccine as indicated.\textsuperscript{3}</td>
</tr>
</tbody>
</table>

References

\textsuperscript{1} Merck Canada Inc. (2015, January 16). PNEUMOVAX® 23: Pneumococcal vaccine, polyvalent, MSD Std. Product Monograph.

\textsuperscript{2} National Advisory Committee on Immunization. (2015, April). Re-immunization with polysaccharide 23-valent pneumococcal vaccine (Pneu-P-23).


