Pneumococcal Vaccine, 23-valent Polysaccharide: PNEUMOVAX® 23

Revision Date: August 10, 2015

Please consult the Product Monograph[1] for further information about the vaccine.

Manufacturer	Merck Canada Inc.
Off license use	None
Indications for use of provincially funded vaccine	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. • All individuals 65 years of age and older.[2] **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] **Note:** Individuals prescribed eculizumab (Soliris®) are at increased risk of serious infections, especially with encapsulated bacteria, such as *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

	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

	➢ 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)[1,3] when possible.
Possible reactions	**Local reactions:** • Soreness, erythema, swelling, local induration, decreased limb mobility and peripheral edema in the injected limb.[1,3] • Rarely, cellulitis-like reactions have been reported.[1,3] **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.[1,3] **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.[1,9]

	• 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.[11] Refer to: *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers*.[12]
Pregnancy	Pregnant women with conditions that are a risk for IPD should receive pneumococcal vaccine as indicated.[3]
Lactation	Breastfeeding women with conditions that are a risk for IPD should receive pneumococcal vaccine as indicated.[3]

References

[1] Merck Canada Inc. (2015, January 16). PNEUMOVAX® 23: Pneumococcal vaccine, polyvalent, MSD Std. *Product Monograph*.

[2] National Advisory Committee on Immunization. (2015, April). Re-immunization with polysaccharide 23-valent pneumococcal vaccine (Pneu-P-23).

[3] National Advisory Committee on Immunization. (2015). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html

[4] Public Health Agency of Canada. (2014). An Advisory Committee Statement National Advisory Committee on Immunization: Update on the Use of Pneumococcal Vaccines: Addition of Asthma as a High-Risk Condition.

[5] Alexion Pharma International Sàrl. (2013-05-31). [Pr]SOLIRIS® (eculizumab). *Product Monograph.*

[6] Alberta Health. *Public Health Notifiable Disease Management Guidelines - Pneumococcal disease, invasive*. www.health.alberta.ca/professionals/notifiable-diseases-guide.html

[7] Centers for Disease Control and Prevention. (2013, June 28). Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine among Children Aged 6 – 18 Years with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report, 62(25)*. Retrieved July 12, 2013 from, www.cdc.gov/mmwr/preview/mmwrhtml/mm6225a3.htm

[8] Immunization Action Coalition. (2013, September). Ask the Experts. *Needle Tips 23(3)*. Retrieved November 25, 2013 from, www.immunize.org/nslt.d/n57/askexperts.pdf

[9] National Advisory Committee on Immunization. (2013, October). Advisory Committee Statement – Statement on the use of conjugate pneumococcal vaccine – 13 valent in adults (Pneu-C-13). Canadian Communicable Disease Report: 39(ACS-5).

[10] Centers of Disease Control and Prevention. (2012, October). Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine for adults with immunocompromising conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report 61(40).* Retrieved June 7, 2013 from, www.cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm

[11] Grabenstein, J. D. (2012). *ImmunoFacts: Vaccines and Immunologic Drugs 2013*. St. Louis, MO: Wolters Kluwer Health.

[12] Alberta Health. (2016, December). *Adverse Events Following Immunization (AEFI), Policy for Alberta Immunization Providers.* www.health.alberta.ca/documents/AIP-Adverse-Events-Following-Immunization-Policy.pdf

