# Pneumococcal Vaccine, 15-valent Conjugate (Pneu-C15): Vaxneuvance®

BIOLOGICAL PAGE

Alberta Health Services
Communicable Disease Control

| | | | |
|---|---|---|---|
| **Section 7** | Biological Product Information | **Standard # 07.292** | |
| **Created and approved by** | Provincial Immunization Program Standards and Quality | | |
| **Approval date** | June 24, 2024 | **Revised** | |

| | **Vaxneuvance® Pneumococcal 15-valent Conjugate Vaccine (Pneu-C15)** |
|---|---|
| **Manufacturer** | Merck Canada Inc. |
| **Biological Classification** | Inactivated: Conjugate |
| **Indications for Provincially Funded Vaccine** | Children two months up to and including 59 months of age who are not considered high risk for invasive pneumococcal disease (IPD).<br><br>**Note:**<br>Regardless of previous IPD, pneumococcal conjugate vaccine is recommended. If a series is interrupted due to IPD, the series should be continued once the individual has recovered.<br><br>For disease investigation and reporting requirements, refer to Alberta public health disease management guidelines : pneumococcal disease, invasive (IPD)<br><br>**Note: Prevnar 20™ is recommended for the following groups:**<br>Children and adults who belong to one or more of the groups listed below may be at a higher risk for IPD and should receive Pneu-C20 vaccine instead of Pneu-C15:<br><br>*Populations with sustained high rates of IPD*:<br>• Residents of continuing care homes and senior supportive living accommodations.<br>• First Nations, Métis, and Inuit peoples regardless of where they live.<br><br>*Individuals with the following medical conditions*, see Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression:<br>• Asplenia/hyposplenism (functional or anatomic)<br>• Chronic cardiac disease (including congenital heart disease and cyanotic heart disease)<br>• Chronic cerebral spinal fluid (CSF) leak.<br>• Chronic liver disease (including biliary atresia, fatty liver, hepatitis B and C and hepatic cirrhosis due to any cause).<br>• Chronic neurologic condition that may impair clearance of oral secretions.<br>• Chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).<br>• Chronic renal disease, including nephrotic syndrome, on dialysis or with renal transplant.<br>• Cochlear implants (candidates and recipients).<br>• Congenital immunodeficiencies 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.<br>• Diabetes mellitus<br>• Hematopoietic stem cell transplant (HSCT) and/or CAR T-cell therapy recipients. See Immunization for Child HSCT Recipients or Immunization for Adult HSCT Recipients.<br>• HIV infection.<br>• Immunosuppressive therapy including:<br>  ○ long term use of long-term corticosteroids,<br>  ○ chemotherapy (undergoing or anticipating),<br>  ○ radiation therapy (undergoing or anticipating), |

| | |
|---|---|
| | ○ post-organ transplant therapy,<br>○ biologic and non-biologic immunosuppressive therapies for, examples include:<br>▪ inflammatory arthropathies, e.g., systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,<br>▪ inflammatory dermatological conditions, e.g., psoriasis, severe atopic dermatitis, and eczema, and<br>▪ inflammatory bowel disease, e.g., Crohn's disease, ulcerative colitis<br>**Note:** Individuals prescribed eculizumab (Soliris®) or other complement C5 inhibitors are at increased risk of serious infections, especially with encapsulated bacteria, such as *Streptococcus pneumoniae*; therefore, they should receive Pneu-C20 vaccine at two weeks before receiving the first doses of complement C5 inhibitors if possible.<br>• Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma, Hodgkin's disease, and multiple myeloma.<br>• Malignant solid organ tumors either currently or within past 5 years.<br>• Sickle-cell disease and other hemoglobinopathies.<br>• Solid organ or islet transplant (SOT) candidates and recipients. See Immunization for Children Expecting Solid Organ Transplant before 18 Months of Age (Accelerated) and Immunization for Children Expecting Solid Organ Transplant at 18 Months of Age or Older (Catch-up Schedule).<br><br>*Individuals who*:<br>• Have an alcohol use disorder<br>• Use illicit drugs<br>• Smoke or vape<br>• Have poor indoor air quality in the home (including, but not limited to, secondhand smoke, wood fired stoves)<br>• Are experiencing houselessness<br>○ 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. |
| **Serology** | N/A |
| **Schedule** | **Healthy Children Routine Schedule**<br>**Note:** Healthy Children who started a series with another pneumococcal conjugate vaccine (i.e., Pneu-C, Pneu-C10 or Pneu-C13) should complete their series with Pneu-C15 conjugate vaccine. Previous doses will be counted, and the series will not be restarted.<br><br>Starting immunization at:<br>• 2 months up to and including 11 months of age (3 doses)<br>○ Dose 1: 2 months of age<br>○ Dose 2: 4 months of age<br>○ Dose 3: 12 months of age<br>• 12 months up to and including 23 months of age (2 doses)<br>○ Dose 1: primary dose – day 0<br>○ Dose 2: reinforcing dose – eight weeks after 1st dose<br>• 24 months up to and including 59 months of age<br>○ One dose<br>**Note**:<br>• Dose 1 may be administered to infants as early as six weeks of age.<br>• The recommended interval between doses 1 and 2 for children younger than one year of age is eight weeks. However, the interval may be shortened to four weeks.<br>• For children 2 months up to and including 11 months of age, the third dose should be given in the second year of life (12 months of age or older), and at least 8 weeks from second dose.<br>• The minimum interval between doses for children receiving immunization after 12 months of age is eight weeks. |

<table>
<tr><th></th><th colspan="3">Vaxneuvance® Pneumococcal 15-valent Conjugate Vaccine (Pneu-C15)</th></tr>
<tr><td></td><td colspan="3">Interrupted Schedule for Healthy Children</td></tr>
<tr><td></td><td># of Previous Doses</td><td>Completion of Primary Series (4 to 8 weeks apart)</td><td>Reinforcing Dose (given in the second year of life at least 8 weeks after last dose)</td></tr>
<tr><td></td><td colspan="3">3 months up to and including 11 months at re-presentation</td></tr>
<tr><td></td><td>0 previous doses</td><td>2 doses</td><td>1 dose</td></tr>
<tr><td></td><td>1 previous dose</td><td>1 dose</td><td>1 dose</td></tr>
<tr><td></td><td>2 previous doses</td><td>Primary series complete</td><td>1 dose</td></tr>
<tr><td></td><td colspan="3">12 months up to and including 23 months at re-presentation</td></tr>
<tr><td></td><td>0 to 1 previous dose prior to 12 months</td><td>1 dose</td><td>1 dose</td></tr>
<tr><td></td><td>2 previous doses prior to 12 months</td><td>Primary series complete</td><td>1 dose</td></tr>
<tr><td></td><td>1 previous dose at 12 months or later</td><td>Primary series complete</td><td>1 dose</td></tr>
<tr><td></td><td colspan="3">24 months up to and including 59 months at re-presentation</td></tr>
<tr><td></td><td>Any incomplete age-appropriate schedule</td><td colspan="2">1 dose</td></tr>
<tr><td></td><td colspan="3">Notes:<ul><li>For individuals that belong to a population that puts them at higher risk of IPD, the series should be completed with Pneu-C20, following the appropriate number of doses and intervals for Pneu-C20.</li><li>An individual who does not belong to a population that puts them at a higher risk of IPD and who previously completed a pneumococcal conjugate vaccine series is considered up to date and is not eligible for any additional doses.</li><li>Children who are eligible for Pneu-C20 may receive Pneu-C15 in the event Pneu-C20 supply is not available. Once Pneu-C20 supply is available, eligible children can receive Pneu-C20 following that vaccine's schedule to complete their pneumococcal series. Previous doses will be counted, and the series will not be restarted.</li></ul></td></tr>
<tr><td>Preferred Use</td><td colspan="3">N/A</td></tr>
<tr><td>Dose</td><td colspan="3">0.5 mL</td></tr>
<tr><td>Route</td><td colspan="3">Intramuscular injection</td></tr>
<tr><td>Contraindications/ Precautions</td><td colspan="3">Contraindications<ul><li>History of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or any diphtheria toxoid-containing vaccine.</li></ul>Precautions<ul><li>Pneu-C15 will not protect against S. pneumoniae serotypes not included in the vaccine.</li></ul></td></tr>
</table>

| | Vaxneuvance® Pneumococcal 15-valent Conjugate Vaccine (Pneu-C15) |
|---|---|
| **Possible Reactions** | **Common:**<br>• Pain, erythema, swelling and induration at injection site<br>• Fatigue<br>• Headache<br>• Arthralgia<br>• Myalgia<br>• Decreased appetite<br>• Irritability<br>• Somnolence<br>• Fever<br>• Urticaria<br>**Rare:**<br>• Anaphylaxis<br>• Allergic reaction<br>As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information. |
| **Pregnancy** | Pregnant women at high risk of IPD due to chronic medical conditions should receive Pneu-C20 vaccine if indicated, following an assessment of risks and benefits. |
| **Lactation** | It is not known whether this vaccine is excreted in human milk. If at high risk of IPD due to chronic medical conditions, consider Prevnar 20™ vaccine following an assessment of the risks and benefits. |
| **Composition** | Each 0.5 mL dose contains:<br>• Conjugated to 30 micrograms diphtheria ($CRM_{197}$) carrier protein:<br>  ○ 2 micrograms of polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F<br>  ○ 4 micrograms of polysaccharide serotype 6B<br>• Nonmedicinal ingredients:<br>  ○ 125 mcg aluminum (as aluminum phosphate adjuvant)<br>  ○ 1.55 mg L-histidine<br>  ○ 1 mg polysorbate 204.5 mg sodium chloride<br>  ○ Water for injection |
| **Blood/Blood Products** | Does not contain any blood products. |
| **Bovine/Porcine Products** | Does not contain any bovine or porcine products. |
| **Latex** | No latex in the product. |
| **Interchangeability** | Children who have started their immunization series with a different pneumococcal conjugate vaccine may complete their series using Pneu-C15. There is no need to restart the immunization series. |
| **Administration with Other Products** | Can be administered concomitantly with 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 used. |
| **Appearance** | Should be shaken vigorously horizontally prior to administration to obtain an opalescent suspension. |
| **Storage** | • Store at 2°C to 8°C.<br>• Do not freeze. Protect from light.<br>• Administer as soon as possible after removal from cold chain. |
| **Vaccine Code** | PNEU-C15 |
| **Antigen Code** | PNEUMO-C |
| **Licensed for** | Individuals 6 weeks of age and older. |

| | Vaxneuvance® Pneumococcal 15-valent Conjugate Vaccine (Pneu-C15) |
|---|---|
| **Notes** | • 2024 June 24: Introduced into routine program for children and replacing Pneu-C13. |
| **Related Resources** | Pneumococcal Conjugate (PNEU-C15) Vaccine Information Sheet (105625). |

**References**


1. Alberta Health. Public Health Division. Alberta immunization Policy. (2024 June 24). Pneumococcal Vaccine, 15-valent Conjugate: Vaxneuvance®.
2. Alberta Health, Government of Alberta. Alberta Public Health Disease Management Guidelines: Invasive Pneumococcal Disease. 2021; Available from: https://open.alberta.ca/dataset/67a2161b-d849-4fd4-8c02-9a1be7c65809/resource/9750e6df-ed5d-48b5-93b4-bd70a9b41b00/download/health-phdmg-pneumoccocal-disease-invasive-2021-09.pdf
3. Alexion Pharma GmbH. Soliris (eculizumab for injection) product monograph [Internet]. Available from: https://pdf.hres.ca/dpd_pm/00053762.PDF
4. Email communication from Merck. 04 June 2024
5. Merck Canada Inc. VAXNEUVANCE® Pneumococcal 15-valent Conjugate vaccine [Internet]. 2023. Available from: https://www.merck.ca/en/wp-content/uploads/sites/20/2022/06/VAXNEUVANCE-PM_E.pdf
6. National Advisory Committee on Immunization. Recommendations for public health programs on the use of pneumococcal vaccines in children, including the use of 15-valent and 20-valent conjugate vaccines [Internet]. 2024. Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-recommendations-public-health-programs-use-pneumococcal-vaccines-children-including-use-15-valent-20-valent-conjugate-vaccines/naci-statement-2024-03-11.pdf
7. National Advisory Committee on Immunization. Canadian Immunization Guide - Canada.ca [Internet]. Public Health Agency of Canada. 2023. Available from: https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html
8. National Advisory Committee on Immunization. Public health level recommendations on the use of pneumococcal vaccines in adults, including the use of 15 valent and 20 valent conjugate vaccines [Internet]. 2023. Available from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/public-health-level-recommendations-use-pneumococcal-vaccines-adults-including-use-15-valent-20-valent-conjugate-vaccines.html