

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

## BIOLOGICAL PAGE

<b>Section 7</b>	Biological Product Information	<b>Standard # 07.292</b>
<b>Created and approved by</b>	Provincial Immunization Program Standards and Quality	
<b>Approval date</b>	June 24, 2024	<b>Revised</b>

	Vaxneuvance® Pneumococcal 15-valent Conjugate Vaccine (Pneu-C15)
<b>Manufacturer</b>	Merck Canada Inc.
<b>Biological Classification</b>	Inactivated: Conjugate
<b>Indications for Provincially Funded Vaccine</b>	<p>Children 2 months up to and including 59 months of age who are <b>not</b> considered high risk for invasive pneumococcal disease (IPD).</p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>For disease investigation and reporting requirements, refer to <a href="#">Alberta public health disease management guidelines : pneumococcal disease, invasive (IPD)</a></li> <li>Prenar 20, rather than Pneu-C15, is recommended for the following high risk groups for IPD:</li> </ul> <p><b>Populations with sustained high rates of IPD:</b></p> <ul style="list-style-type: none"> <li>Residents of continuing care homes and senior supportive living accommodations.</li> <li>First Nations, Métis, and Inuit peoples regardless of where they live.</li> </ul> <p><b>Individuals with the following medical conditions, see <a href="#">Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression</a>:</b></p> <ul style="list-style-type: none"> <li>Asplenia/hyposplenism (functional or anatomic)</li> <li>Chronic cardiac disease (including congenital heart disease and cyanotic heart disease)</li> <li>Chronic cerebral spinal fluid (CSF) leak.</li> <li>Chronic liver disease (including biliary atresia, fatty liver, hepatitis B and C and hepatic cirrhosis due to any cause).</li> <li>Chronic neurologic condition that may impair clearance of oral secretions.</li> <li>Chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).</li> <li>Chronic renal disease, including nephrotic syndrome, on dialysis or with renal transplant.</li> <li>Cochlear implants (candidates and recipients).</li> <li>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.</li> <li>Diabetes mellitus</li> <li>Hematopoietic stem cell transplant (HSCT) and/or CAR T-cell therapy recipients. See <a href="#">Immunization for Child HSCT Recipients</a> or <a href="#">Immunization for Adult HSCT Recipients</a>.</li> <li>HIV infection.</li> <li>Immunosuppressive therapy including: <ul style="list-style-type: none"> <li>long term use of long-term corticosteroids,</li> <li>chemotherapy (undergoing or anticipating),</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>▪ radiation therapy (undergoing or anticipating),</li> <li>▪ post-organ transplant therapy,</li> <li>▪ biologic and non-biologic immunosuppressive therapies for, examples include:               <ul style="list-style-type: none"> <li>• Inflammatory arthropathies, example, systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,</li> <li>• Inflammatory dermatological conditions, example, psoriasis, severe atopic dermatitis, and eczema, and</li> <li>• Inflammatory bowel disease, example., Crohn's disease, ulcerative colitis</li> </ul> </li> </ul> <p><b>Note:</b> Individuals prescribed eculizumab (Soliris®) or other complement C5 inhibitors are at increased risk of serious infections, especially with encapsulated bacteria, such as <i>Streptococcus pneumoniae</i>; therefore, they should receive Pneu-C20 vaccine at two weeks before receiving the first doses of complement C5 inhibitors if possible.</p> <ul style="list-style-type: none"> <li>○ Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma, Hodgkin's disease, and multiple myeloma.</li> <li>○ Malignant solid organ tumors either currently or within past 5 years.</li> <li>○ Sickle-cell disease and other hemoglobinopathies.</li> <li>○ 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).</li> </ul> <p><b>Individuals who:</b></p> <ul style="list-style-type: none"> <li>○ Have an alcohol use disorder</li> <li>○ Use illicit drugs</li> <li>○ Smoke or vape</li> <li>○ Have poor indoor air quality in the home (including, but not limited to, secondhand smoke, wood fired stoves)</li> <li>○ Are experiencing houselessness               <ul style="list-style-type: none"> <li>▪ 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.</li> </ul> </li> </ul>
<b>Serology</b>	N/A
<b>Schedule</b>	<p><b>Healthy Children Routine Schedule</b></p> <ul style="list-style-type: none"> <li>• Healthy children who started a series with another pneumococcal conjugate vaccine (such as 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.</li> </ul> <p><b>Starting immunization at:</b></p> <ul style="list-style-type: none"> <li>• 2 months up to and including 11 months of age (3 dose series)               <ul style="list-style-type: none"> <li>○ Dose 1: 2 months of age</li> <li>○ Dose 2: 4 months of age</li> <li>○ Dose 3: 12 months of age</li> </ul> </li> <li>• 12 months up to and including 23 months of age (2 dose series)               <ul style="list-style-type: none"> <li>○ Dose 1: primary dose – day 0</li> <li>○ Dose 2: reinforcing dose – 8 weeks after first dose</li> </ul> </li> <li>• 24 months up to and including 59 months of age               <ul style="list-style-type: none"> <li>○ 1 dose</li> </ul> </li> </ul>

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

### Note:

- Dose 1 may be administered to infants as early as 6 weeks of age.
- The recommended interval between doses 1 and 2 for children younger than 1 year of age is 8 weeks; however, the interval may be shortened to 4 weeks.
- For children 2 months up to and including 11 months of age, give the third dose in the second year of life (12 months of age or older) and at least 8 weeks from the second dose.
- The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.

### Interrupted Schedule for Healthy Children

# of Previous Doses	Primary Series Completion (4 to 8 weeks apart)	Reinforcing Dose (given in the second year of life and at least 8 weeks after last dose)
<b>3 months up to and including 11 months at re-presentation</b>		
0 previous doses	2 doses	1 dose
1 previous dose	1 dose	1 dose
2 previous doses	Primary series complete	1 dose
<b>12 months up to and including 23 months at re-presentation</b>		
0 to 1 previous dose prior to 12 months	1 dose	1 dose
2 previous doses prior to 12 months	Primary series complete	1 dose
1 previous dose at 12 months or later	Primary series complete	1 dose
<b>24 months up to and including 59 months at re-presentation</b>		
Any incomplete age- appropriate schedule	1 dose	

### Note:

- Individuals identified to be at higher risk of IPD should complete a series of Pneu-C20.
  - Follow scheduling for Pneu-C20.
- Individuals not identified to be at a higher risk of IPD and who previously completed a pneumococcal conjugate vaccine series are not eligible for any additional doses of Pneu-C15. They are considered up to date.
- Children eligible for Pneu-C20 may receive Pneu-C15 in the event Pneu-C20 supply is not available.

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	<ul style="list-style-type: none"> <li>Once Pneu-C20 supply is available, eligible children can receive Pneu-C20.</li> <li>Follow Pneu-C20 vaccine schedule to complete pneumococcal series.</li> <li>Previous doses will be counted and the series will not be restarted.</li> </ul>
Preferred Use	N/A
Dose	0.5 mL
Route	Intramuscular injection
Contraindications/ Precautions	<b>Contraindications</b> <ul style="list-style-type: none"> <li>History of a severe allergic reaction such as anaphylaxis to any component of the vaccine or any diphtheria toxoid-containing vaccine.</li> </ul> <p><b>Note:</b> Pneu-C15 will not protect against <i>S. pneumoniae</i> serotypes not included in the vaccine.</p>
Possible Reactions	<b>Common:</b> <ul style="list-style-type: none"> <li>Pain, erythema, swelling and induration at injection site</li> <li>Fatigue</li> <li>Headache</li> <li>Arthralgia</li> <li>Myalgia</li> <li>Decreased appetite</li> <li>Irritability</li> <li>Somnolence</li> <li>Fever</li> <li>Urticaria</li> </ul> <b>Rare:</b> <ul style="list-style-type: none"> <li>Anaphylaxis</li> <li>Allergic reaction</li> <li>As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.</li> </ul>
Pregnancy	N/A
Lactation	N/A
Composition	Each 0.5 mL dose contains: <ul style="list-style-type: none"> <li>Conjugated to 30 micrograms diphtheria (CRM<sub>197</sub>) carrier protein: <ul style="list-style-type: none"> <li>2 micrograms of polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F</li> <li>4 micrograms of polysaccharide serotype 6B</li> </ul> </li> <li>Nonmedicinal ingredients: <ul style="list-style-type: none"> <li>125 mcg aluminum (as aluminum phosphate adjuvant)</li> <li>1.55 mg L-histidine</li> <li>1 mg polysorbate 20/4.5 mg sodium chloride</li> <li>Water for injection</li> </ul> </li> </ul>
Blood/Blood Products	Does not contain any blood products.
Bovine/Porcine Products	Does not contain any bovine or porcine products.

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<b>Latex</b>	Does not contain latex.
<b>Interchangeability</b>	<ul style="list-style-type: none"> <li>Healthy children who started a series with another pneumococcal conjugate vaccine such as Pneu-C, Pneu-C10 or Pneu-C13 should complete their series with Pneu-C15 conjugate vaccine. <ul style="list-style-type: none"> <li>Previous doses will be counted, and the series will not be restarted.</li> </ul> </li> </ul>
<b>Administration with Other Products</b>	<p>May be given at the same time as other inactivated and live vaccines.</p> <ul style="list-style-type: none"> <li>Use a separate needle and syringe for each vaccine.</li> <li>The same limb may be used, if necessary, but use different sites on the limb.</li> </ul>
<b>Appearance</b>	Shake vigorously and horizontally prior to administration to obtain an opalescent suspension.
<b>Storage</b>	<ul style="list-style-type: none"> <li>Store at 2°C to 8°C.</li> <li>Do not freeze.</li> <li>Protect from light.</li> <li>Administer as soon as possible after removal from cold chain.</li> </ul>
<b>Vaccine Code</b>	PNEU-C15
<b>Antigen Code</b>	PNEUMO-C
<b>Licensed for</b>	Individuals 6 weeks of age and older.
<b>Notes</b>	<ul style="list-style-type: none"> <li>2024 June 24: Introduced into routine program for children to replace PNEU-C13.</li> </ul>
<b>Related Resources</b>	<a href="#">Pneumococcal Vaccine, 15-valent Conjugate (Pneu-C15) Information Sheet</a>
<b>References</b> <p>Alberta Health. (2024, June 24). Pneumococcal Vaccine, 15-valent Conjugate: Vaxneuvance. In Alberta Immunization Policy: Biological Products. Government of Alberta.</p> <p>Alberta Health. (2021, September). Invasive Pneumococcal Disease. In Alberta Public Health Disease Management Guidelines. Government of Alberta.</p> <p>Alexion Pharma GmbH. (2024, July 24). Soliris (eculizumab for injection). Health Canada drug product database. <a href="https://pdf.hres.ca/dpd_pm/00076446.PDF">https://pdf.hres.ca/dpd_pm/00076446.PDF</a></p> <p>Merck Canada Inc. Email communication June 04, 2024</p> <p>Merck Canada Inc. (2024, June 26). VAXNEUVANCE® Pneumococcal 15-valent Conjugate vaccine. Health Canada drug product database. <a href="https://pdf.hres.ca/dpd_pm/00076109.PDF">https://pdf.hres.ca/dpd_pm/00076109.PDF</a></p> <p>National Advisory Committee on Immunization. (2023, February 24). Recommendations for public health programs on the use of pneumococcal vaccines in children, including the use of 15-valent and 20-valent conjugate vaccines. An advisory committee statement. Public Health Agency of Canada.</p> <p>National Advisory Committee on Immunization. (2023, February 24). Public health level recommendations on the use of pneumococcal vaccines in adults, including the use of 15 valent and 20 valent conjugate vaccines. An advisory committee statement. Public Health Agency of Canada.</p> <p>Public Health Agency of Canada. (2024, May). Pneumococcal vaccines. In <i>Canadian immunization Guide</i>. Government of Canada.</p>	