Pneumococcal 13-valent Conjugate Vaccine Biological Page

Section 7: Biological Product Information

Standard #: 07.291

Created by: Province-wide Immunization Program Standards and Quality

Approved by: Province-wide Immunization Program Standards and Quality

Approval Date: February 1, 2012

Revised: February 1, 2017

Prevnar® 13

Manufacturer

T.M. Wyeth, Pfizer Canada Inc.

Biological Classification

Inactivated:

Indications for Provincially Funded Vaccine

Healthy Children:
- 2 months up to and including 59 months of age.
- Catch-up: children up to and including 59 months of age who have completed pneumococcal conjugate immunization with a conjugate vaccine other than Prevnar®13 should be offered a single dose of Prevnar® 13 vaccine if they present prior to their 5th birthday (preferably at their preschool immunization appointment).

High Risk Individuals:
- 2 months up to and including 17 years of age
  - asplenia/hyposplenism (functional or anatomic)
  - chronic cardiac disease
  - chronic cerebrospinal fluid (CSF) leaks
  - chronic liver disease (including hepatitis B and C and hepatic cirrhosis due to any cause).
  - chronic neurologic conditions that my impair clearance of oral secretions
  - chronic pulmonary disease (excluding asthma unless treated with high-dose oral corticosteroid therapy)
  - chronic renal disease including nephrotic syndrome
  - cochlear implants (candidates and recipients)
  - congenital immunodeficiencies involving any part of the immune system including B-lymphocyte immunity (humoral), T-lymphocyte (cell) mediated immunity, complement system (properdin or factor D deficiencies) or phagocytic functions
  - diabetes mellitus, poorly controlled
  - hematopoietic stem cell transplant (HSCT) recipients - see Standard for Immunization of Transplant Candidates and Recipients #08.304
  - HIV infection
  - immunosuppressive therapy including use of (or anticipated use of) long term oral corticosteroids, chemotherapy, radiation therapy, post-organ transplant therapy, and certain anti-rheumatic drugs
  - Individuals prescribed eculizumab (Soliris®) should receive Prevnar® 13 at least 2 weeks before receiving the first doses of Soliris® if possible. If this is not possible the individual may still receive the vaccine but the immune response may be diminished.
  - malignant neoplasms including leukemia, lymphoma, Hodgkin’s disease and multiple myeloma
  - sickle-cell disease and other hemoglobinopathies
  - solid organ transplant or islet transplant (SOT) candidates and recipient - see Standard for Immunization of Transplant Candidates and

Note:
For questions related to Travel and or For Sale vaccine refer to AHS Travel Health and Contracted Immunization Services resources.
**Prevnar® 13**

- **18 years and older:**
  - asplenia (anatomic or functional)
  - chronic CSF leak
  - cochlear implants (candidates or recipients)
  - congenital immunodeficiencies involving any part of the immune system including B-lymphocyte immunity (humoral), T-lymphocyte (cell) mediated immunity, complement system (properdin or factor D deficiencies) or phagocytic functions
  - hematopoietic stem cell transplant (HSCT) recipients - see Standard for Immunization of Transplant Candidates and Recipients #08.304
  - HIV infection
  - immunosuppressive therapy including use of (or anticipated use of) long term oral corticosteroids, chemotherapy, radiation therapy, post-organ transplant therapy, and biologic and non-biologic immunosuppressive therapies for rheumatologic and other inflammatory diseases
  - malignant neoplasms including leukemia, lymphoma,
  - Individuals prescribed eculizumab (Soliris®) should receive Prevnar® 13 at least 2 weeks before receiving the first doses of Soliris® if possible. If this is not possible the individual may still receive the vaccine but the immune response may be diminished.
  - sickle cell disease and other hemoglobinopathies
  - solid organ transplant (SOT) candidates or recipients - see Standard for Immunization of Transplant Candidates and Recipients #08.304

**Notes:**

- Previous invasive pneumococcal disease (IPD) does not confer immunity or preclude immunization with pneumococcal conjugate vaccine. If a series is interrupted due to IPD, the series should be completed once the individual has recovered.
- Individuals 2 years of age and older at high risk may be eligible for both pneumococcal 13-valent conjugate vaccine and pneumococcal polysaccharide vaccine (see Pneumococcal Polysaccharide Vaccine Biological Page for indications).

<table>
<thead>
<tr>
<th>Schedule</th>
<th>General Schedule Considerations:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>healthy children routinely receive 3 doses scheduled at 2, 4 and 12 months of age</td>
</tr>
<tr>
<td></td>
<td>high risk individuals (see indications section for definition of high risk) routinely receive 4 doses scheduled at 2, 4, 6 and 12 months of age. <strong>The exception to this is SOT candidates and recipients and HSCT recipients.</strong> Refer to Standard for Immunization of Transplant Candidates and Recipients #08.304 for details regarding scheduling and spacing intervals between doses.</td>
</tr>
<tr>
<td></td>
<td><strong>Aboriginal children</strong> beginning immunization at younger than 7 months should receive four doses of vaccine at 2, 4, 6 and 12 months similar to children under 7 months who are high risk.</td>
</tr>
<tr>
<td></td>
<td>fewer doses of vaccine may be needed for individuals who are not immunized according to the routine immunization schedule.</td>
</tr>
<tr>
<td></td>
<td>the following pages contain detailed routine and interrupted schedule charts, including recommended spacing between doses, for healthy and high risk individuals.</td>
</tr>
</tbody>
</table>

**Catch-up:**

- children up to and including 59 months of age who have completed pneumococcal conjugate immunization with a conjugate vaccine other than Prevnar® 13 should be offered a single dose of Prevnar® 13 if they present prior to their 5th birthday (preferably at their preschool appointment)
  - the catch-up dose must be at least 8 weeks after the last dose of
Pneumococcal Conjugate Vaccine

Routine Schedule for Healthy Children (3 dose series):

<table>
<thead>
<tr>
<th>Age at Presentation</th>
<th>Primary Series (4 to 8 weeks apart)</th>
<th>Reinforcing Dose (given in the second year of life at least 8 weeks after last dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months up to and including 11 months</td>
<td>2 doses Routinely given at the 2 and 4 month clinic visit.</td>
<td>1 dose Routinely given at the 12 month clinic visit.</td>
</tr>
<tr>
<td>12 months up to and including 23 months</td>
<td>1 dose</td>
<td>1 dose</td>
</tr>
<tr>
<td>24 months up to and including 59 months of age</td>
<td>1 dose</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
- For children who began immunization with a pneumococcal conjugate vaccine other than Prevnar® 13, immunization can be completed using Prevnar® 13. There is no need to restart the vaccine series.
- All children that have completed a vaccine series using a pneumococcal conjugate vaccine other than Prevnar® 13 should receive a single dose of Prevnar® 13 prior to their fifth birthday (preferably during their preschool immunization appointment).
- Minimum age to receive Prevnar® 13 is 6 weeks.
- The recommended interval between doses for children less than 1 year of age is 8 weeks. However, the interval can be shortened to 4 weeks if necessary.
- The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.

Interrupted Schedule for Healthy Children (3 dose series):

<table>
<thead>
<tr>
<th># of Previous Doses</th>
<th>Completion of Primary Series (4 to 8 weeks apart)</th>
<th>Reinforcing Dose (given in the second year of life at least 8 weeks after last dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months up to and including 11 months at re-presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 previous doses</td>
<td>2 doses</td>
<td>1 dose</td>
</tr>
<tr>
<td>1 previous dose</td>
<td>1 dose</td>
<td>1 dose</td>
</tr>
<tr>
<td>2 previous doses</td>
<td>Primary series complete</td>
<td>1 dose</td>
</tr>
</tbody>
</table>

| 12 months up to and including 23 months at re-presentation | | |
| 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 |

| 24 months up to and including 59 months at re-presentation | | |
| Any incomplete age appropriate schedule | | 1 dose |

Notes:
- The recommended interval between doses for children less than 1 year of age is 8 weeks. However, the interval can be shortened to 4 weeks if necessary.
- The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.
## Prevnar® 13

### Routine Schedule for High Risk Individuals (4 dose series):

<table>
<thead>
<tr>
<th>Age at Presentation</th>
<th>Primary Series (4 to 8 weeks apart)</th>
<th>Reinforcing Dose (given in the second year of life at least 8 weeks after last dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 months up to and including 6 months</td>
<td>3 doses Routinely given at the 2, 4 and 6 month clinic visit.</td>
<td>1 dose Routinely given at the 12 month clinic visit.</td>
</tr>
<tr>
<td>7 months up to and including 11 months</td>
<td>2 doses</td>
<td>1 dose</td>
</tr>
<tr>
<td>12 months up to and including 59 months</td>
<td>1 dose</td>
<td>1 dose</td>
</tr>
<tr>
<td>5 years and older</td>
<td>1 dose</td>
<td></td>
</tr>
</tbody>
</table>

### Notes:

- For children who began immunization with a pneumococcal conjugate vaccine other than Prevnar® 13, immunization can be completed using Prevnar® 13. There is no need to restart the vaccine series.
- All children that have completed a vaccine series using a pneumococcal conjugate vaccine other than Prevnar® 13 should receive a single dose of Prevnar® 13 prior to their fifth birthday (preferably during their preschool immunization appointment).
- Minimum age to receive Prevnar® 13 is 6 weeks.
- The recommended interval between doses for children less than 1 year of age is 8 weeks. However, the interval can be shortened to 4 weeks if necessary.
- The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.
- If possible vaccine should be administered at least 14 days before splenectomy or initiation of immunosuppressive therapy.
- 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 8 weeks between the 2 vaccines. However if pneumococcal polysaccharide vaccine has already been administered, there must be an interval between doses as specified below:
  - Children 2 years up to and including 17 years of age: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 8 weeks after the pneumococcal polysaccharide vaccine
  - Adults 18 years of age and older: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 1 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.
### Prevnar® 13

**Interrupted Schedule for High Risk Individuals (4 dose series):**

<table>
<thead>
<tr>
<th># of Previous Doses</th>
<th>Completion of Primary Series (4 to 8 weeks apart)</th>
<th>Reinforcing Dose (given in the second year of life at least 8 weeks after last dose)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months up to and including 6 months at re-presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 previous doses</td>
<td>3 doses</td>
<td>1 dose</td>
</tr>
<tr>
<td>1 previous dose</td>
<td>2 doses</td>
<td>1 dose</td>
</tr>
<tr>
<td>2 previous doses</td>
<td>1 dose</td>
<td>1 dose</td>
</tr>
<tr>
<td>7 months up to and including 11 months at re-presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 previous doses</td>
<td>2 doses</td>
<td>1 dose</td>
</tr>
<tr>
<td>1 to 2 previous doses prior to 7 months</td>
<td>1 dose</td>
<td>1 dose</td>
</tr>
<tr>
<td>12 months up to and including 59 months at re-presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 to 1 previous dose prior to 12 months</td>
<td>1 dose</td>
<td>1 dose</td>
</tr>
<tr>
<td>2 to 3 previous doses prior to 12 months</td>
<td>Primary series complete</td>
<td>1 dose</td>
</tr>
<tr>
<td>1 previous dose at 12 months or later</td>
<td>Primary series complete</td>
<td>1 dose</td>
</tr>
<tr>
<td>5 years of age and older</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any incomplete age appropriate schedule</td>
<td>1 dose</td>
<td>1 dose</td>
</tr>
</tbody>
</table>

**Notes:**

- For children who began immunization with a pneumococcal conjugate vaccine other than Prevnar® 13, immunization can be completed using Prevnar® 13. There is no need to restart the vaccine series.
- All children that have completed a vaccine series using a pneumococcal conjugate vaccine other than Prevnar® 13 should receive a single dose of Prevnar® 13 prior to their fifth birthday (preferably during their preschool immunization appointment).
- Minimum age to receive Prevnar® 13 is 6 weeks.
- The recommended interval between doses for children less than 1 year of age is 8 weeks. However, the interval can be shortened to 4 weeks if necessary.
- The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.
- If possible vaccine should be administered at least 14 days before splenectomy or initiation of immunosuppressive therapy.
- Individuals 2 years of age and older at high risk may be eligible for both pneumococcal 13-valent conjugate vaccine and pneumococcal polysaccharide vaccine (see Pneumococcal Polysaccharide Vaccine Biological Page for indications).
- 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 8 weeks between the 2 vaccines. However if pneumococcal polysaccharide vaccine has already been administered, there must be an interval between doses as specified below:
  - Children 2 years up to and including 17 years of age: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 8 weeks after the pneumococcal polysaccharide vaccine
  - Adults 18 years of age and older: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 1 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.
### Prevnar® 13

<table>
<thead>
<tr>
<th>Preferred Use</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>0.5 mL</td>
</tr>
<tr>
<td>Route</td>
<td>IM</td>
</tr>
</tbody>
</table>
| Contraindications/Precautions | This vaccine should not be given to individuals who:  
- have had an anaphylactic reaction to a previous dose of this vaccine  
- have a known hypersensitivity to any component of the vaccine  
- present with a serious acute febrile illness:  
  - recommendations should be provided for these individuals to be immunized when their symptoms have resolved.  
  - individuals with non-serious febrile illness may be immunized. |
| Possible Reactions | **Common:**  
- injection site pain, redness, warmth, swelling and local induration  
- fever (greater than 39°C)  
- chills  
- decreased appetite  
- irritability  
- drowsiness/increased sleep or restless sleep/decreased sleep  
- headache  
- muscle pain, joint pain  
- diarrhea and vomiting  
- rash  

**Rare:**  
- seizure (including febrile seizures)  
- crying  
- urticaria or urticaria like rash  
- hypersensitivity reaction including facial edema, dyspnea and bronchospasm  
- hypotonic-hyporesponsive episode  
- lymphadenopathy localized to the region of the injection site  
- anaphylaxis  
- erythema multiforme  
- As with any immunization, unexpected or unusual side effects can occur. Refer to the 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:  
- 2.2 mcg each of saccharide for *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F and 23F  
- 4.4 mcg saccharide for *Streptococcus pneumoniae* serotype 6B  
- non-toxic diphtheria CRM 197 carrier protein  
- aluminum phosphate  
- sodium chloride  
- succinic acid  
- polysorbate 80  
- sterile water for injection |
| Blood/Blood Products | Contains no human blood or blood products. |
| Bovine/Porcine Products | Contains no bovine or porcine products. Casamino acids are used in the manufacturing process. |
| Latex | There is no latex in the vaccine or the vaccine packaging. |
### Interchangeability

Children who have started their immunization schedule with a different pneumococcal conjugate vaccine may complete the series using Prevnar® 13 vaccine. There is no need to restart the immunization series.

### Administration with Other Products

- 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 8 weeks between the 2 vaccines. However, if pneumococcal polysaccharide vaccine has already been administered, there must be an interval between doses as specified below:
  - Children 2 years up to and including 17 years of age: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 8 weeks after the pneumococcal polysaccharide vaccine.
  - Adults 18 years of age and older: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 1 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.
- Prevnar® 13 vaccine can be given at the same time as other inactivated and live vaccine 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.

### Appearance

- White suspension; the vaccine should be shaken well to obtain a homogeneous solution.

### 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

- PNEU-C13

### Antigen Code

- PNEUMO-C

### Licensed for

- Individuals 6 weeks and older

### Notes:

- Prevnar® 13 vaccine eligibility criteria was expanded to include more high risk categories and eligibility criteria was changed to 2 months up to and including 59 months (September 2014).
- Prevnar® 13 vaccine eligibility was expanded to include HIV infected individuals 6 years of age and older beginning February 1, 2012.
- Prevnar® 13 vaccine replaced the Prevnar® vaccine in the routine childhood immunization schedule on July 1, 2010. A catch-up program for children who had completed a pneumococcal conjugate series using Prevnar® vaccine was included in this program change.
- The routine immunization schedule in Alberta changed from a 4 dose to a 3 dose schedule for healthy children on July 1, 2010. High risk children continue to receive 4 doses.
- Prevnar® was introduced into the routine childhood immunization schedule in Alberta on September 1, 2002. The vaccine was offered at the 2, 4, 6 and 18 month immunization appointments.

### Related Documents:

- Pneumococcal Conjugate Vaccine Information Sheet (104502) (September 9, 2014)
- Decision Document for Tool to Assist with Pneumococcal Immunization (November 10, 2014)
Prevnar® 13

References: