Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) 
ActHIB®

DESCRIPTION
ActHIB®, Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate), produced by Sanofi Pasteur SA, is a sterile, lyophilized powder which is reconstituted with either saline diluent (0.4% Sodium Chloride) or Tripedia®, Sanofi Pasteur Inc. Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) (when reconstituted known as TriHIB®) for intramuscular administration only. The vaccine consists of the Haemophilus b capsular polysaccharide (polyribosyl-ribitol-phosphate, PRP), a high molecular weight polymer prepared from the Haemophilus influenzae type b (Hib) strain 1482 grown in a semi-synthetic medium, covalently bound to tetanus toxoid. (1) The lyophilized ActHIB vaccine powder and saline diluent contain no preservative. The tetanus toxoid is prepared by extraction, ammonium sulfate purification, and formalin inactivation of the toxin from cultures of Clostridium tetani (Harvard strain) grown in a modified Mueller and Miller medium. (2) The culture medium contains milk derived raw materials (casein derivatives). Further manufacturing process steps reduce residual formaldehyde to levels below 0.5 micrograms (mcg) per dose by calculation. The toxoid is filter sterilized prior to the conjugation process. Potency of ActHIB vaccine is specified on each lot by limits on the content of PRP polysaccharide and protein in each dose and the proportion of polysaccharide and protein in the vaccine which is characterized as high molecular weight conjugate.

When ActHIB is reconstituted with saline diluent (0.4% Sodium Chloride), each 0.5 mL dose is formulated to contain 10 mcg of purified capsular polysaccharide conjugated to 24 mcg of inactivated tetanus toxoid, and 8.5% of sucrose.

When ActHIB is reconstituted with Tripedia vaccine to formulate TriHIBit vaccine, each 0.5 mL dose contains 10 mcg of purified capsular polysaccharide conjugated to 24 mcg of inactivated tetanus toxoid, 8.5% of sucrose, 6.7 LI of diphtheria toxoid, 5 LI of tetanus toxoid, and 46.8 mcg of pertussis antigens. Tripedia vaccine (vial presentation 0.6 mL) is formulated without preservatives but contains a trace amount of thimerosal [(mercury derivative), (=0.3 mcg mercury/dose)] from the manufacturing process. (Refer to product insert for Tripedia vaccine.)

CLINICAL PHARMACOLOGY
H influenzae type b was the leading cause of invasive bacterial disease among children in the United States prior to licensing of Haemophilus b conjugate vaccines.

The response to ActHIB vaccine is typical of a T-dependent immune response to antigen. The prominent isotype of anti-capsular PRP antibody induced by ActHIB vaccine is IgG. (3) A booster response for IgG has been demonstrated in children 12 months of age or older who previously received two or three doses of ActHIB vaccine. Bactericidal activity against H influenzae type b was demonstrated in serum after immunization and correlated with the anti-PRP antibody response induced by ActHIB vaccine. (4)

Antibody to H influenzae capsular polysaccharide (anti-PRP) titer of >1.0 mcg/mL following vaccination with unconjugated PRP vaccine correlated with long-term protection against invasive H influenzae type b disease in children older than 24 months of age. (5) Although the relevance of this threshold to clinical protection after immunization with conjugate vaccines is not known, particularly in light of the induced, immunologic memory, this level continues to be considered as indicative of long-term protection. (6) In clinical studies, ActHIB vaccine induced, on average, anti-PRP levels ≥1.0 mcg/mL in 90% of infants after the primary series (2, 4, and 6 months) and in more than 98% of infants following a booster dose given at 15 to 19 months of age. (4)

Two clinical trials supported by the National Institutes of Health (NIH) have compared the anti-PRP antibody responses to three Haemophilus b conjugate vaccines in racially mixed populations of children. These studies were done in Tennessee (7) (TABLE 1) and in Minnesota, Missouri, and Texas (8) (TABLE 2) in infants immunized with ActHIB vaccine and other Haemophilus b conjugate vaccines at 2, 4, and 6 months of age. All Haemophilus b conjugate vaccines were administered concomitantly with Poliovirus Vaccine Live Oral and whole cell DTP vaccines at separate sites. Neither Poliovirus Vaccine Live Oral nor whole cell DTP vaccines are licensed or distributed in the US.

### TABLE 1: Anti-PRP Antibody Responses Following a Two or Three Dose Series of a Haemophilus b Vaccine at 2, 4, and 6 Months of Age - Tennessee (7)

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>N°</th>
<th>PRE-IMMUNIZATION AT 2 MONTHS</th>
<th>POST SECOND IMMUNIZATION AT 6 MONTHS</th>
<th>POST THIRD IMMUNIZATION AT 7 MONTHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRP-Tb</td>
<td>65</td>
<td>0.10</td>
<td>0.30</td>
<td>3.64</td>
</tr>
<tr>
<td>PRP-OMPc</td>
<td>64</td>
<td>0.11</td>
<td>0.84</td>
<td>N/A</td>
</tr>
<tr>
<td>HibOCc</td>
<td>61</td>
<td>0.07</td>
<td>0.13</td>
<td>3.08</td>
</tr>
</tbody>
</table>

- a N = Number of Children
- b Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)
- c Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)
- d Seroconversion after the recommended 2-dose primary immunization series is shown
- e Haemophilus b Conjugate Vaccine (Diphtheria CRM197 Protein Conjugate)
- N/A Not applicable in this comparison trial although third dose data have been published (7)

- f Haemophilus b Conjugate Vaccine (Diphtheria CRM197 Protein Conjugate)

### TABLE 2: Anti-PRP Antibody Responses Following a Two or Three Dose Series of a Haemophilus b Vaccine at 2, 4, and 6 Months of Age - Minnesota, Missouri, and Texas (8)

<table>
<thead>
<tr>
<th>VACCINE</th>
<th>N°</th>
<th>PRE-IMMUNIZATION</th>
<th>POST SECOND IMMUNIZATION</th>
<th>POST THIRD IMMUNIZATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRP-Tb</td>
<td>142</td>
<td>0.25</td>
<td>1.25</td>
<td>6.37</td>
</tr>
<tr>
<td>PRP-OMPc</td>
<td>149</td>
<td>0.18</td>
<td>4.00</td>
<td>N/A</td>
</tr>
<tr>
<td>HibOCc</td>
<td>167</td>
<td>0.17</td>
<td>0.45</td>
<td>6.31</td>
</tr>
</tbody>
</table>

- a N = Number of Children
- b Sera were obtained after the third dose from 86 and 110 infants, in PRP-T and HibOCc vaccine groups, respectively
- c Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)
- d Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)
- e Seroconversion after the recommended 2-dose primary immunization series is shown
- f Haemophilus b Conjugate Vaccine (Diphtheria CRM197 Protein Conjugate)
- N/A Not applicable in this comparison trial although third dose data have been published (8)

### TABLE 3: Anti-PRP Antibody Responses in 12- to 24-month-old Children Immunized with a Single Dose of ActHIB (10)

<table>
<thead>
<tr>
<th>AGE GROUP</th>
<th>N°</th>
<th>PRE-IMMUNIZATION</th>
<th>POST IMMUNIZATION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>GMC CONCENTRATION (mcg/mL)</td>
<td>% SUBJECTS WITH &gt;1.0 mcg/mL</td>
</tr>
<tr>
<td>12 to 15 months</td>
<td>256</td>
<td>0.06</td>
<td>5.12</td>
</tr>
<tr>
<td>17 to 24 months</td>
<td>61</td>
<td>0.10</td>
<td>4.40</td>
</tr>
</tbody>
</table>

- a N = Number of Children
- b Post immunization responses measured at approximately 1 month after vaccination

ActHIB vaccine has been found to be immunogenic in children with sickle cell anemia, a condition which may cause increased susceptibility to Haemophilus b disease. Following two doses of ActHIB vaccine given at two-month intervals, 89% of these children (mean age 11 months) had anti-PRP antibody titers of ≥1.0 mcg/mL. This is comparable to anti-PRP antibody levels demonstrated in normal children of similar age following two doses of ActHIB vaccine. (11)
TriHIBit Vaccine (ActHIB vaccine combined with Tripedia vaccine by reconstitution) Randomized comparative clinical trials demonstrated that the anti-PRP response achieved in 15- to 20-month-old children 1 month after one dose of TriHIBit vaccine (ActHIB vaccine reconstituted with Tripedia vaccine) was similar to that achieved when the ActHIB and Tripedia vaccines were given concomitantly at different sites with separate needles and syringes (TABLE 4). All children had received three doses of a Haemophilus b conjugate vaccine (HiB TITER or ActHIB vaccine) and three doses of a whole-cell DTP vaccine prior to entry into this clinical trial.

**TABLE 4**: Anti-PRP Responses in 15- to 20-month-old Children Following Immunization with TriHIBit Vaccine Compared to ActHIB Vaccine and Tripedia Vaccine Given Concomitantly at Separate Sites (10)

<table>
<thead>
<tr>
<th></th>
<th>Pre-Dose</th>
<th>Post-Dose (1 month post-vaccination)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TriHIBit vaccine</td>
<td>Separate Injections</td>
</tr>
<tr>
<td>N</td>
<td>88</td>
<td>94</td>
</tr>
<tr>
<td>Anti-PRP (mcg/mL)</td>
<td>0.89</td>
<td>1.15</td>
</tr>
<tr>
<td>% &gt;1 mcg/mL</td>
<td>45.50</td>
<td>33.20</td>
</tr>
</tbody>
</table>

a  ActHIB and Tripedia administered concomitantly at separate sites  
N  Number of Children

For data on the antibody responses to diphtheria, tetanus and pertussis (PT and FHA) antigens in this study, refer to the Tripedia vaccine product insert.

**INDICATIONS AND USAGE**

ActHIB vaccine is indicated for the active immunization of infants and children 2 months through 5 years of age for the prevention of invasive disease caused by H influenzae type b.

TriHIBit vaccine. ActHIB vaccine combined with Tripedia vaccine by reconstitution, is indicated for the active immunization of children 15 through 18 months of age for prevention of invasive disease caused by H influenzae type b and diphtheria, tetanus and pertussis.

Vaccination with ActHIB vaccine reconstituted with saline diluent (0.4% Sodium Chloride) or Tripedia vaccine (TriHIBit vaccine) may not protect 100% of individuals.

**CONTRAINDICATIONS**

ActHIB vaccine is contraindicated in children with a history of hypersensitivity to any component of the vaccine and to any component of Tripedia vaccine when it is used to reconstitute ActHIB. Any contraindication for Tripedia vaccine is a contraindication for TriHIBit vaccine, ActHIB vaccine reconstituted with Tripedia vaccine. (*Refer to product insert for Tripedia vaccine.*)

TriHIBit vaccine (ActHIB reconstituted with Tripedia) is contraindicated in children who have shown symptoms of encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of a pertussis-containing vaccine that is not attributable to another identifiable cause. TriHIBit is contraindicated in children who have a progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy. Pertussis-containing vaccines should not be administered to individuals with these conditions until a treatment regimen has been established and the condition has stabilized.

**WARNINGS**

The stopper of the diluent vial contains natural rubber latex which may cause allergic reactions. The lyophilized vaccine vial is not made with natural rubber latex.

If ActHIB vaccine or ActHIB vaccine reconstituted with Tripedia vaccine (TriHIBit vaccine) is administered to immunosuppressed persons or persons receiving immunosuppressive therapy, the expected antibody responses may not be obtained. This includes patients with asymptomatic or symptomatic HIV infection (12), severe combined immunodeficiency, hypogammaglobulinemia, or agammaglobulinemia; altered immune states due to diseases such as leukemia, lymphoma, or generalized malignancy; or an immune system compromised by treatment with corticosteroids, alkylating drugs, antilymphocytes, or radiation. (*Refer to product insert for Tripedia vaccine.*)

**PRECAUTIONS**

**GENERAL**

Care is to be taken by the health-care provider for the safe and effective use of this vaccine.

Epinephrine injection (1:1000) must be immediately available should an anaphylactic or other allergic reactions occur due to any component of the vaccine.

Prior to an injection of any vaccine, all known precautions should be taken to prevent adverse reactions. This includes a review of the patient’s history with respect to possible sensitivity and any previous adverse reactions to the vaccine or similar vaccines, and to possible sensitivity to natural rubber latex, previous immunization history, current health status (see **CONTRAINDICATIONS** and **WARNINGS** sections), and a current knowledge of the literature concerning the use of the vaccine under consideration. (*Refer to product insert for Tripedia vaccine.*)
Use with caution in patients on anticoagulant therapy.

**CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY**

ActHIB vaccine reconstituted with saline diluent (0.4% Sodium Chloride) or TriHIBit vaccine (TriHIBit vaccine) has not been evaluated for its carcinogenic, mutagenic potential or impairment of fertility.

**PREGNANCY CATEGORY C**

Animal reproduction studies have not been conducted with ActHIB vaccine reconstituted with saline diluent (0.4% Sodium Chloride) or TriHIBit vaccine (TriHIBit vaccine). It is also not known whether ActHIB vaccine reconstituted with saline diluent (0.4% Sodium Chloride) or TriHIBit vaccine (TriHIBit vaccine) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ActHIB vaccine reconstituted with saline diluent (0.4% Sodium Chloride) or TriHIBit vaccine (TriHIBit vaccine) is not approved for use in pregnant women.

**PEDIATRIC USE**

Safety and effectiveness of ActHIB vaccine reconstituted with saline diluent (0.4% Sodium Chloride) in infants below the age of 6 weeks have not been established. (See DOSAGE AND ADMINISTRATION section.)

Safety and effectiveness of TriHIBit vaccine, ActHIB vaccine reconstituted with TriHIBit vaccine, in infants below the age of 15 months have not been established. (See DOSAGE AND ADMINISTRATION section.)

**ADVERSE REACTIONS**

More than 7,000 infants and young children (≤2 years of age) have received at least one dose of ActHIB vaccine during US clinical trials. Of these, 1,064 subjects 12 to 24 months of age who received ActHIB vaccine alone reported no serious or life threatening adverse reactions.

Adverse reactions commonly associated with a first ActHIB vaccine immunization of children 12 to 15 months of age who were previously unimmunized with any Haemophilus b conjugate vaccine, include local pain, redness, and swelling at the injection site. Systemic reactions include fever, irritability, and lethargy (4) (10).

Adverse reactions associated with ActHIB vaccine generally subsided after 24 hours and usually do not persist beyond 48 hours after immunization.

In a US trial, safety of TriHIBit vaccine, ActHIB vaccine combined with TriHIBit vaccine by reconstitution, in 110 children aged 15 to 20 months was compared to ActHIB vaccine given with TriHIBit vaccine at separate sites to 110 children. All children received three doses of Haemophilus b conjugate vaccine (ActHIB vaccine or HibTITER) and three doses of whole-cell DTP at approximately 2, 4, and 6 months of age. Local reactions were typically mild and usually resolved within the 24 to 48 hour period after immunization. The most common local reactions were pain and tenderness at the injection site. Systemic reactions occurring were usually mild and resolved within 72 hours of immunization. The reaction rates were similar to those observed in TABLE 5 when TriHIBit vaccine, ActHIB vaccine reconstituted with TriHIBit vaccine, was administered and when TriHIBit vaccine was administered alone as a booster. (10)

The number of subjects studied with TriHIBit vaccine, ActHIB vaccine combined with TriHIBit vaccine by reconstitution, was inadequate to detect rare serious adverse events.

**Reporting of Adverse Events**

Reporting by the parent or guardian of all adverse events occurring after vaccine administration should be encouraged. Adverse events following immunization with vaccine should be reported by the health-care provider to the US Department of Health and Human Services (DHHS) Vaccine Adverse Event Reporting System (VAERS). Reporting forms and information about reporting requirements or completion of the form can be obtained from VAERS through a toll-free number 1-800-822-7967. (15) (16) (18)

**Health-care providers also should report these events to Sanofi Pasteur Inc.,**
**Discovery Drive, Swiftwater, PA 18370 or call 1-800-822-2463.**

**Post-Marketing Experience**

The following events have been spontaneously reported during the post-approval use of ActHIB. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

- Immune System Disorders: Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)
- Nervous System Disorders: Convulsions
- General Disorders and Administration Site Conditions: Extensive limb swelling, peripheral edema, pruritus, and rash

**DOSAGE AND ADMINISTRATION**

**For intramuscular injection only**

The ActHIB vaccine, reconstituted with saline diluent (0.4% Sodium Chloride), appears clear and colorless. TriHIBit vaccine, the reconstituted vaccine using TriHIBit vaccine, is a homogenous white suspension.

Parenteral drug products should be inspected visually for particulate matter and/or discoloration prior to administration, whenever solution and container permit. If these conditions exist, the vaccine should not be administered.

**RECONSTITUTION**

ActHIB is to be reconstituted only with the accompanying saline diluent (0.4% Sodium Chloride) or TriHIBit vaccine to formulate TriHIBit vaccine. TriHIBit vaccine, ActHIB vaccine combined with TriHIBit vaccine by reconstitution, should not be administered to infants younger than 15 months of age.

To prepare ActHIB vaccine, withdraw 0.6 mL of saline diluent (0.4% Sodium Chloride) and inject into the vial of lyophilized ActHIB vaccine. Agitate the vial to ensure complete reconstitution. The vaccine will appear clear and colorless. Withdraw a 0.5 mL dose of the reconstituted vaccine and inject intramuscularly. After reconstitution with saline diluent (0.4% Sodium Chloride), ActHIB vaccine should be administered promptly or stored refrigerated between 2° to 8°C (35° to 46°F) and administered within 24 hours. If the vaccine is not administered promptly, agitate the vial again before injection. Refer to Figures 1, 2, 3, 4, and 5.

To prepare TriHIBit vaccine, thoroughly agitate the vial of Sanofi Pasteur Inc. TriHIBit vaccine then withdraw 0.6 mL and inject into the vial of lyophilized ActHIB vaccine. After reconstitution and thorough agitation, the combined vaccines will appear whith in color. Withdraw a 0.5 mL dose of the combined vaccines and inject intramuscularly. TriHIBit vaccine (ActHIB vaccine reconstituted with TriHIBit vaccine) should be administered within 30 minutes of reconstitution. Refer to Figures 1, 2, 3, 4, and 5.

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>6 Hrs. Post-dose</th>
<th>24 Hrs. Post-dose</th>
<th>48 Hrs. Post-dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Separate Injections</td>
<td>Separate Injections</td>
<td>Separate Injections</td>
</tr>
<tr>
<td></td>
<td>TriHIBit Vaccine N=110</td>
<td>TriHIBit Vaccine N=110</td>
<td>TriHIBit Vaccine N=110</td>
</tr>
<tr>
<td></td>
<td>TriHIBit Vaccine N=110</td>
<td>TriHIBit Vaccine N=110</td>
<td>TriHIBit Vaccine N=110</td>
</tr>
<tr>
<td>Local (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tenderness</td>
<td>17.3/20.0</td>
<td>19.1</td>
<td>8.2/8.2</td>
</tr>
<tr>
<td>Erythema &gt;1&quot;</td>
<td>0.9/0.0</td>
<td>3.6</td>
<td>2.7/0.9</td>
</tr>
<tr>
<td>Indurationb</td>
<td>3.6/5.5</td>
<td>2.7</td>
<td>2.7/3.6</td>
</tr>
<tr>
<td>Swelling</td>
<td>3.6/3.6</td>
<td>3.6</td>
<td>2.7/1.8</td>
</tr>
<tr>
<td>Systemic (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever&lt;102.2°F</td>
<td>0</td>
<td>2.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Irritability</td>
<td>27.3</td>
<td>22.9</td>
<td>20.9</td>
</tr>
<tr>
<td>Drowsiness</td>
<td>36.4</td>
<td>30.3</td>
<td>17.3</td>
</tr>
<tr>
<td>Anorexia</td>
<td>12.7</td>
<td>9.2</td>
<td>10.0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0.9</td>
<td>1.8</td>
<td>0.9</td>
</tr>
<tr>
<td>Persistent Cry</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unusual Cry</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* TriHIBit vaccine, ActHIB vaccine combined with TriHIBit vaccine by reconstitution.
* TriHIBit vaccine injection site/ActHIB vaccine injection site
* Induration is defined as hardness with or without swelling

TriHIBit vaccine, ActHIB vaccine combined with TriHIBit vaccine by reconstitution, was administered to approximately 850 children, aged 15 to 20 months. All children received three doses of a Haemophilus b conjugate vaccine (ActHIB vaccine or HibTITER) and three doses of whole-cell DTP at approximately 2, 4, and 6 months of age. Local reactions were typically mild and usually resolved within the 24 to 48 hour period after immunization. The most common local reactions were pain and tenderness at the injection site. Systemic reactions occurring were usually mild and resolved within 72 hours of immunization. The reaction rates were similar to those observed in TABLE 5 when TriHIBit vaccine, ActHIB vaccine reconstituted with TriHIBit vaccine, was administered and when TriHIBit vaccine was administered alone as a booster. (10)
Instructions for Reconstitution of ActHIB Vaccine with Saline Diluent (0.4% Sodium Chloride) or Tripedia Vaccine (TriHIBit Vaccine)

Figure 1. Agitate vial prior to disinfecting the vial stopper to avoid possible contamination.

Figure 2. Withdraw 0.6 mL of 0.4% Sodium Chloride or Tripedia vaccine as indicated.

Figure 3. Cleanse the ActHIB vaccine stopper, insert the syringe needle into the vial, and inject the total volume of diluent.

Figure 4. Agitate vial thoroughly.

Figure 5. After reconstitution, cleanse vial stopper. Using a new needle and syringe, withdraw 0.5 mL of reconstituted vaccine and administer intramuscularly.

Before injection, the skin over the site to be injected should be cleansed with a suitable germicide.

Each dose of ActHIB vaccine reconstituted with saline diluent (0.4% Sodium Chloride) or Tripedia vaccine (TriHIBit vaccine) is administered intramuscularly in the outer aspect of the vastus lateralis (mid-thigh) or deltoid. The vaccine should not be injected into the gluteal area or areas where may be a nerve trunk.

A 0.5 mL dose of ActHIB is approved for intramuscular administration in infants and children, 2 months through 5 years of age as a 4-dose series. The series consists of a primary immunization course of 3 doses administered at 2, 4, and 6 months of age, followed by one booster dose, administered at 15-18 months of age. The booster dose at 15-18 months of age may be given as TriHIBit vaccine (ActHIB reconstituted with Tripedia).

For previously unvaccinated children, the number of doses of Haemophilus b Conjugate Vaccine needed depends on the age at which the immunization series is begun. A previously unvaccinated infant, 7 to 11 months of age, should receive as primary immunizations, two doses of Haemophilus b Conjugate Vaccine at 8-week intervals, followed by a booster dose at 15 to 18 months of age. A previously unvaccinated child 12 to 14 months of age should receive one dose of Haemophilus b Conjugate Vaccine followed by a booster dose at 15 to 18 months of age (doses to be separated by an interval of 8 weeks). A previously unvaccinated child 15 months through 5 years of age should receive one dose of ActHIB vaccine.

Preterm infants should be vaccinated according to their chronological age from birth. (19)

Interruption of the recommended schedule with a delay between doses should not interfere with the final immunity achieved with ActHIB vaccine reconstituted with saline diluent (0.4% Sodium Chloride) or with Tripedia vaccine (TriHIBit vaccine). There is no need to start the series over again, regardless of the time elapsed between doses.

HOW SUPPLIED
ActHIB Vaccine Reconstituted with Saline Diluent (0.4% Sodium Chloride)
Single-dose, lyophilized vaccine vial (NDC 49281-547-56) packaged with single-dose diluent vial (NDC 49281-546-05). Supplied as package of 5 vials each (NDC 49281-545-05).

TriHIBit Vaccine, ActHIB Vaccine Reconstituted with Tripedia Vaccine
Single-dose, lyophilized vaccine vial (NDC 49281-545-50) packaged with single-dose diluent vial of Tripedia vaccine (NDC 49281-298-01). Supplied as package of 5 vials each (NDC 49281-597-05).

STORAGE
Store lyophilized vaccine packaged with saline diluent (0.4% Sodium Chloride) or Tripedia vaccine at 2° to 8°C (35° to 46°F). DO NOT FREEZE.

REFERENCES
4. Data on file, Sanofi Pasteur SA.
10. Data on file, Sanofi Pasteur Inc.