

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use ActHIB safely and effectively. See full prescribing information for ActHIB.

**ActHIB® Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) Solution for Intramuscular Injection**  
Initial U.S. Approval: 1993

-----**RECENT MAJOR CHANGES**-----

Warnings and Precautions, Latex (5.2) – Removed [3/2016]

-----**INDICATIONS AND USAGE**-----

- ActHIB is a vaccine indicated for the prevention of invasive disease caused by *Haemophilus influenzae* type b. ActHIB vaccine is approved for use as a four dose series in infants and children 2 months through 5 years of age (1)

-----**DOSAGE AND ADMINISTRATION**-----

Four dose series (0.5 mL each) by intramuscular injection:

- A three dose primary series administered at 2, 4 and 6 months of age. (2.1)
- A single booster dose administered at 15-18 months of age. (2.1)

-----**DOSAGE FORMS AND STRENGTHS**-----

- Solution for injection: lyophilized powder to be reconstituted in supplied 0.4% Sodium Chloride diluent. A single dose, after reconstitution is 0.5 mL (3)

-----**CONTRAINDICATIONS**-----

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any *H. influenzae* type b or tetanus toxoid-containing vaccine or any component of ActHIB vaccine. (4)

-----**WARNINGS AND PRECAUTIONS**-----

- If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the potential benefits and risks of giving ActHIB vaccine must be evaluated. (5.2)

-----**ADVERSE REACTIONS**-----

- Following administration of ActHIB vaccine in children 2-20 months of age, rates of adverse reactions varied by dose number and age of recipients:
  - In children 15-20 months of age tenderness (20%) was the most common local reaction following a single dose. (6.1)
  - The most frequent systemic reactions after any dose for children 2 months to 16 months of age were fussiness/irritability (75%), inconsolable crying (58%) and decreased activity/lethargy (51%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Pharmacovigilance Department, Sanofi Pasteur Inc., Discovery Drive, Swiftwater, PA 18370 at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or <http://vaers.hhs.gov>.

Revised: XXXX XXXX

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1 **FULL PRESCRIBING INFORMATION:**

2

3 **1 INDICATIONS AND USAGE**

4 ActHIB is a vaccine indicated for the prevention of invasive disease caused by *Haemophilus*  
5 *influenzae* type b. ActHIB is approved for use in children 2 months through 5 years of age.

6

7 **2 DOSAGE AND ADMINISTRATION**

8

9 **2.1 Immunization Series**

10 ActHIB vaccine is to be administered as a 4 dose series (0.5mL per dose) as:

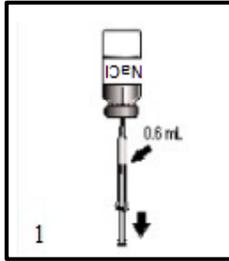
- 11 • A primary three dose series of a single dose at 2, 4, and 6 months of age.  
12 • A single booster dose at 15 through 18 months of age.

13

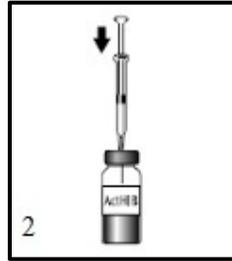
14 **2.2 Reconstitution**

15 ActHIB vaccine is a solution for injection supplied as single-dose vials of lyophilized vaccine to  
16 be reconstituted only with the accompanying saline diluent (0.4% Sodium Chloride). To  
17 reconstitute ActHIB vaccine, withdraw 0.6 mL of saline diluent and inject into the vial of  
18 lyophilized ActHIB vaccine. Agitate the vial to ensure complete reconstitution. The reconstituted  
19 ActHIB vaccine will appear clear and colorless. Withdraw a 0.5 mL dose of the reconstituted  
20 vaccine and inject intramuscularly. After reconstitution, if ActHIB vaccine is not administered  
21 promptly store at 2° to 8°C (35° to 46°F) and administer within 24 hours. Stored vaccine should  
22 be re-agitated prior to injection. Refer to Figures 1, 2, 3, and 4.

1 **Instructions for Reconstitution of ActHIB Vaccine with Saline Diluent (0.4% Sodium**  
2 **Chloride)**



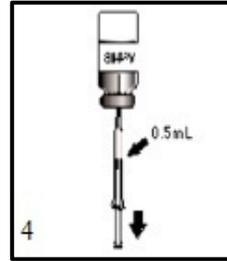
**Figure 1.**  
Disinfect the diluent vial stopper, inject the needle and withdraw 0.6 mL of 0.4% Sodium Chloride diluent as indicated.



**Figure 2.**  
Cleanse the ActHIB vaccine stopper, insert the syringe needle into the vial, and inject the total volume of diluent.



**Figure 3.**  
Agitate vial thoroughly.



**Figure 4.**  
After reconstitution, withdraw 0.5 mL of reconstituted vaccine and administer **intramuscularly**.

3

4

5 **2.3 Administration**

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

9

10 ActHIB vaccine is administered as a single dose (0.5 mL) by intramuscular injection into the  
11 anterolateral aspect of the thigh or deltoid.

12

13 Do not administer this product intravenously, intradermally, or subcutaneously.

14

15 ActHIB vaccine should not be mixed in the same syringe with other parenteral products.

1

### 2 **3 DOSAGE FORMS AND STRENGTHS**

3 ActHIB vaccine is a solution for injection supplied as a lyophilized powder to be reconstituted  
4 with the supplied 0.4% Sodium Chloride diluent. A single dose, after reconstitution is 0.5 mL.

5

### 6 **4 CONTRAINDICATIONS**

7

#### 8 **4.1 Hypersensitivity**

9 Severe allergic reaction (e.g., anaphylaxis) after a previous dose of any *H. influenzae* type b- or  
10 tetanus toxoid-containing vaccine or any component of the vaccine is a contraindication to  
11 administration of ActHIB vaccine.[see Description (11)]

12

### 13 **5 WARNINGS AND PRECAUTIONS**

14

#### 15 **5.1 Prevention and Management of Acute Allergic Reactions**

16 Epinephrine and other appropriate agents must be available should an acute anaphylactic reaction  
17 occur.

18

19

#### 20 **5.2 Guillain-Barré Syndrome**

21 If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing  
22 tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including ActHIB  
23 vaccine, should be based on careful consideration of the potential benefits and possible risks.

1

2 **5.3 Altered Immunocompetence**

3 In immunosuppressed persons, including those receiving immunosuppressive therapy, the  
4 expected antibody responses may not be obtained.

5

6 **5.4 Limitations of Vaccine Effectiveness**

7 Vaccination with ActHIB vaccine may not protect 100% of individuals.

8

9 **5.5 Tetanus Immunization**

10 Immunization with ActHIB vaccine does not substitute for routine tetanus immunization.

11

12 **6 ADVERSE REACTIONS**

13

14 **6.1 Clinical Trials Experience**

15 Because clinical trials are conducted under widely varying conditions, adverse reaction rates  
16 observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials  
17 of another vaccine and may not reflect the rates observed in practice.

18

19 More than 7,000 infants and young children ( $\leq 2$  years of age) have received at least one dose of  
20 ActHIB vaccine during US clinical trials. Of these, 1,064 subjects 12 to 24 months of age who  
21 received ActHIB vaccine alone reported no serious or life threatening adverse reactions.(5) (6)

22

1 Adverse reactions associated with ActHIB vaccine generally subsided after 24 hours and did not  
2 persist beyond 48 hours after immunization.

3

4 In a US trial, the safety of ActHIB vaccine was evaluated in 110 children 15 to 20 months of age.

5 All children received three doses of *Haemophilus influenzae* type b conjugate vaccine (ActHIB

6 vaccine or a previously licensed Haemophilus b conjugate vaccine) at approximately 2, 4, and 6

7 months of age. The incidence of selected solicited injection site and systemic adverse reactions

8 which occurred within 48 hours following the dose of ActHIB vaccine is shown in **Table 1**.

9

10

1 **Table 1: Local and Systemic Reactions at 6, 24, and 48 Hours Following Immunization with**  
2 **ActHIB Vaccine in Children 15 to 20 months old (6)**

Adverse Event	6 Hrs. Post-dose	24 Hrs. Post-dose	48 Hrs. Post-dose
<b>Local (%)</b>	<b>N = 110</b>	<b>N = 110</b>	<b>N = 110</b>
Tenderness	20.0	8.2	0.9
Erythema (>1")	0.0	0.9	0.0
Induration <sup>a</sup>	5.5	3.6	0.9
Swelling	3.6	1.8	0.0
<b>Systemic (%)</b>	<b>N = 103-110</b>	<b>N = 105-110</b>	<b>N = 104-110</b>
Fever (>102.2°F (>39.0°C))	0	1.0	1.9
Irritability	27.3	20.9	12.7
Drowsiness	36.4	17.3	12.7
Anorexia	12.7	10.0	6.4
Vomiting	0.9	0.9	0.9
Persistent cry	0	0	0
Unusual cry	0	0	0

3 <sup>a</sup> Induration is defined as hardness with or without swelling

4

5 In a US clinical trial (P3T06), 1454 children were enrolled and received one dose of ActHIB

6 vaccine at 2 months of age and subsequent doses administered at 4 and 6 months of age

7 (concomitantly with DAPTACEL [a US-licensed diphtheria, tetanus and pertussis vaccine], IPOL

8 [a US-licensed inactivated poliovirus vaccine] and PCV7 [Pneumococcal conjugate vaccine, 7-

9 valent]) vaccines at 2, 4, and 6 months of age and hepatitis B vaccine at 2 and 6 months of age).

10 At 15-16 months of age, 418 children received a 4<sup>th</sup> dose of ActHIB and DAPTACEL vaccines.

11 The most frequent systemic reactions following any dose (>50% of participants) were decreased

12 activity/lethargy, fussiness/irritability, and inconsolable crying.

1 **Table 2: Number (Percentage) of Children with Selected Solicited Systemic Adverse**  
2 **Reactions by Severity Occurring within 0-3 days After Vaccination in Study P3T06**

Systemic Reactions	DAPTACEL + IPOL + ActHIB Vaccines			DAPTACEL + ActHIB Vaccines
	Dose 1 N = 1,390-1,406 %	Dose 2 N = 1,346-1,360 %	Dose 3 N = 1,301-1,312 %	Dose 4 N = 379-381 %
<b>Fever<sup>ab</sup></b>				
≥38.0°C	9.3	16.1	15.8	8.7
>38.5°C	1.6	4.3	5.1	3.2
>39.5°C	0.1	0.4	0.3	0.8
<b>Decreased Activity/Lethargy<sup>c</sup></b>				
Any	51.1	37.4	33.2	24.1
Moderate or Severe	24.3	15.8	12.7	9.2
Severe	1.2	1.4	0.6	0.3
<b>Inconsolable Crying</b>				
Any	58.5	51.4	47.9	36.2
≥1 hour	16.4	16.0	12.2	10.5
>3 hours	2.2	3.4	1.4	1.8
<b>Fussiness/Irritability</b>				
Any	75.8	70.7	67.1	53.8
≥1 hour	33.3	30.5	26.2	19.4
>3 hours	5.6	5.5	4.3	4.5

3 Note. - Ages of study participants ranged from 1.3 to 19.5 months.

4 <sup>a</sup> Fever is based upon actual temperatures recorded with no adjustments to the measurement route.

5 <sup>b</sup> Following Doses 1-3 combined, the proportion of temperature measurements that were taken by axillary, rectal or  
6 other routes, or not recorded were 44.8%, 54.0%, 1.0%, and 0.1%. Following Dose 4, the proportion of temperature  
7 measurements that were taken by axillary, rectal or other routes, or not recorded were 61.1%, 36.6%, 1.7% and 0.5%.

8 <sup>c</sup> Moderate: interferes with or limits usual daily activity; Severe: disabling, not interested in usual daily activity.

9

10 In Study P3T06, within 30 days following any of Doses 1-3 of DAPTACEL + IPOL + ActHIB  
11 vaccines, 50 of 1,455 (3.4%) participants experienced a serious adverse event. One SAE of  
12 seizure with apnea occurring on the day of vaccination with the first dose of the three vaccines  
13 was determined by the investigators as possibly related. Within 30 days following Dose 4, four of

1 418 (1.0%) participants who received DAPTACEL + ActHIB vaccines experienced a serious  
2 adverse event. None was assessed by the investigators as related to the study of vaccines.

3

## 4 **6.2 Postmarketing Experience**

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

- 9 • **Immune system disorders:**

10 Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)

- 11 • **Nervous system disorders:**

12 Convulsions

- 13 • **General disorders and administration site conditions:**

14 Extensive limb swelling, peripheral edema, pruritus, rash

15

## 16 **7 DRUG INTERACTIONS**

17

### 18 **7.1 Concomitant Administration with Other Vaccines**

19 In clinical trials, ActHIB vaccine was administered, at separate sites, concomitantly with one or  
20 more of the following vaccines: DTaP; Measles, Mumps and Rubella vaccine (MMR); Hepatitis  
21 B vaccine; and Inactivated Poliovirus Vaccine (IPV). No impairment of the antibody response to  
22 the individual antigens was demonstrated when ActHIB vaccine was given at the same time but  
23 separate sites with these vaccines. (6)

1

## 2 **7.2 Immunosuppressive Treatments**

3 Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic  
4 drugs, and corticosteroids (used in greater than physiologic doses) may reduce the immune  
5 response to ActHIB vaccine. [See *Altered Immunocompetence* (5.3)]

6

## 7 **8 USE IN SPECIFIC POPULATIONS**

8

### 9 **8.1 Pregnancy**

#### 10 **Pregnancy category C**

11 Animal reproduction studies have not been conducted with ActHIB vaccine. It is also not known  
12 whether ActHIB vaccine can cause fetal harm when administered to a pregnant woman or can  
13 affect reproduction capacity.

14

### 15 **8.4 Pediatric Use**

16 Safety and effectiveness of ActHIB vaccine in infants below the age of 6 weeks have not been  
17 established. [see *Dosage and Administration* (2.1)]

18

## 19 **11 DESCRIPTION**

20

21 ActHIB vaccine is a sterile, lyophilized powder to be reconstituted with saline diluent (0.4%  
22 Sodium Chloride) for intramuscular administration only. The vaccine consists of the *Haemophilus*  
23 *influenzae* type b capsular polysaccharide (polyribosyl-ribitol-phosphate, PRP), a high-molecular-

1 weight polymer prepared from the *H influenzae* type b strain 1482 grown in a semi-synthetic  
2 medium, covalently bound to tetanus toxoid. (10) The lyophilized ActHIB vaccine powder and  
3 saline diluent contain no preservative. The tetanus toxoid is prepared by extraction, ammonium  
4 sulfate purification, and formalin inactivation of the toxin from cultures of *Clostridium tetani*  
5 (Harvard strain) grown in a modified Mueller and Miller medium. (11) The culture medium  
6 contains milk-derived raw materials (casein derivatives). Further manufacturing process steps  
7 reduce residual formaldehyde to levels below 0.5 micrograms (mcg) per dose by calculation. The  
8 toxoid is filter sterilized prior to the conjugation process. Potency of ActHIB vaccine is specified  
9 on each lot by limits on the content of PRP polysaccharide and protein in each dose and the  
10 proportion of polysaccharide and protein in the vaccine that is characterized as high molecular  
11 weight conjugate.

12

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

16

17 The vial stoppers for ActHIB vaccine and diluent are not made with natural rubber latex.

## 18 **12 CLINICAL PHARMACOLOGY**

19

### 20 **12.1 Mechanism of Action**

21 *Haemophilus influenzae* (*H. influenzae*) is a gram-negative coccobacillus. Most strains of *H.*  
22 *influenzae* that cause invasive disease (e.g., sepsis and meningitis) are *H. influenzae* type b.

1 The response to ActHIB vaccine is typical of a T-dependent immune response to antigens. The  
2 prominent isotype of anti-capsular PRP antibody induced by ActHIB vaccine is IgG. (12) A  
3 booster response for IgG has been demonstrated in children 12 months of age or older who  
4 previously received two or three doses of ActHIB vaccine. Bactericidal activity against *H*  
5 *influenzae* type b was demonstrated in serum after immunization and correlated with the anti-PRP  
6 antibody response induced by ActHIB vaccine. (5)

7

8 Antibody titers to *H influenzae* capsular polysaccharide (anti-PRP) of >1.0 mcg/mL following  
9 vaccination with unconjugated PRP vaccine correlated with long-term protection against invasive  
10 *H influenzae* type b disease in children older than 24 months of age. (13) Although the relevance  
11 of this threshold to clinical protection after immunization with conjugate vaccines is not known,  
12 particularly in light of the induced, immunologic memory, this level continues to be considered as  
13 indicative of long-term protection. (14) In clinical studies, ActHIB vaccine induced, on average,  
14 anti-PRP levels  $\geq 1.0$  mcg/mL in 90% of infants after the primary series (2, 4, and 6 months) and  
15 in more than 98% of infants following a booster dose given at 15 to 19 months of age. (5)

16

## 17 **13 NON-CLINICAL TOXICOLOGY**

18

### 19 **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

20 ActHIB vaccine has not been evaluated for its carcinogenic or mutagenic potential or impairment  
21 of fertility.

## 22 **14 CLINICAL STUDIES**

23

### 24 **14.1 Immunogenicity of ActHIB Vaccine in Children 2, 4, and 6 Months of Age**

1 Two clinical trials supported by the National Institutes of Health (NIH) have compared the anti-  
2 PRP antibody responses to three *Haemophilus influenzae* type b conjugate vaccines in racially  
3 mixed populations of children. These studies were done in Tennessee (15) (Table 3) and in  
4 Minnesota, Missouri, and Texas (16) (Table 4) in infants immunized with ActHIB vaccine and  
5 other *Haemophilus influenzae* type b conjugate vaccines at 2, 4, and 6 months of age. All  
6 *Haemophilus influenzae* type b conjugate vaccines were administered concomitantly with OPV  
7 and whole-cell DTP vaccines at separate sites. Neither OPV nor whole-cell DTP vaccines are  
8 licensed or distributed in the US currently.

9

10 **Table 3: Anti-PRP Antibody Responses Following a Two or Three Dose Series of a**  
11 ***Haemophilus influenzae* type b Vaccine at 2, 4, and 6 Months of Age – Tennessee (15)**

Vaccine	N <sup>a</sup>	Geometric Mean Concentration (GMC) (mcg/mL)			Post Third Immunization % ≥1.0 mcg/mL
		Pre- Immunization at 2 months	Post Second Immunization at 6 months	Post Third Immunization at 7 months	
PRP-T <sup>b</sup> (ActHIB vaccine)	65	0.10	0.30	3.64	83%
PRP-OMP <sup>c</sup> (PedvaxHIB®)	64	0.11	0.84	N/A	50% <sup>d</sup>
HbOC <sup>e</sup> (HibTITER®)	61	0.07	0.13	3.08	75%

12

<sup>a</sup> N = Number of children

13

<sup>b</sup> *Haemophilus influenzae* type b Conjugate Vaccine (Tetanus Toxoid Conjugate)

14

<sup>c</sup> *Haemophilus influenzae* type b Conjugate Vaccine (Meningococcal Protein Conjugate)

15

<sup>d</sup> Seroconversion after the recommended 2-dose primary immunization series is shown

16

<sup>e</sup> *Haemophilus influenzae* type b Conjugate Vaccine (Diphtheria CRM<sub>197</sub> Protein Conjugate)

17

N/A Not applicable in this comparison trial although third dose data have been published

18

**Table 4: Anti-PRP Antibody Responses Following a Two or Three Dose Series of a**

19

***Haemophilus influenzae* type b Vaccine at 2, 4, and 6 Months of Age - Minnesota, Missouri,**

20

**and Texas (16)**

Vaccine	N <sup>a</sup>	Geometric Mean Concentration (GMC) (mcg/mL)			Post Third <sup>b</sup> Immunization % ≥1.0 mcg/mL
		Pre- Immunization at 2 months	Post Second Immunization at 6 months	Post Third <sup>b</sup> Immunization at 7 months	
PRP-T <sup>c</sup> (ActHIB vaccine)	142	0.25	1.25	6.37	97%
PRP-OMP <sup>d</sup> (PedvaxHIB)	149	0.18	4.00	N/A	85% <sup>e</sup>
HbOC <sup>f</sup> (HibTITER)	167	0.17	0.45	6.31	90%

1 <sup>a</sup> N = Number of children

2 <sup>b</sup> Sera were obtained after the third dose from 86 and 110 infants, in PRP-T and HbOC vaccine groups, respectively

3 <sup>c</sup> *Haemophilus influenzae* type b Conjugate Vaccine (Tetanus Toxoid Conjugate)

4 <sup>d</sup> *Haemophilus influenzae* type b Conjugate Vaccine (Meningococcal Protein Conjugate)

5 <sup>e</sup> Seroconversion after the recommended 2-dose primary immunization series is shown

6 <sup>f</sup> *Haemophilus influenzae* type b Conjugate Vaccine (Diphtheria CRM<sub>197</sub> Protein Conjugate)

7 N/A Not applicable in this comparison trial although third dose data have been published (16)

8

9 Native American populations have had high rates of *H influenzae* type b disease and have been

10 observed to have low immune responses to *Haemophilus influenzae* type b conjugate vaccines. In

11 a clinical study enrolling Alaskan Native Americans, following the administration of a three dose

12 series of ActHIB vaccine at 6 weeks, 4 months, and 6 months of age, 75% of subjects achieved an

13 anti-PRP antibody titer of ≥1.0 mcg/mL at 7 months of age (1 month after the last vaccination).

14 (17)

15

## 16 14.2 Immunogenicity of ActHIB Vaccine in Children 12 to 24 Months of Age

17 In four separate studies, children 12 to 24 months of age who had not previously received

18 *Haemophilus influenzae* type b conjugate vaccination were immunized with a single dose of

19 ActHIB vaccine (Table 5). Geometric Mean Concentration (GMC) of anti-PRP antibody

1 responses were 5.12 mcg/mL (90% responding with  $\geq 1.0$  mcg/mL) for children 12 to 15 months  
 2 of age and 4.4 mcg/mL (82% responding with  $\geq 1.0$  mcg/mL) for children 17 to 24 months of age.  
 3 (6)

4 **Table 5: Anti-PRP Antibody Responses in 12- to 24-month-old Children Immunized with a**  
 5 **Single Dose of ActHIB**

Age Group	N <sup>a</sup>	Geometric Mean Concentration (GMC) (mcg/mL)		% Subjects With $\geq 1.0$ mcg/mL	
		Pre-Immunization	Post Immunization <sup>b</sup>	Pre Immunization	Post Immunization <sup>b</sup>
12 to 15 months	256	0.06	5.12	1.6	90.2
17 to 24 months	81	0.10	4.40	3.7	81.5

6 <sup>a</sup> N = Number of children

7 <sup>b</sup> Post immunization responses measured at approximately 1 month after vaccination

8

9 ActHIB vaccine has been found to be immunogenic in children with sickle cell anemia, a  
 10 condition that may cause increased susceptibility to *Haemophilus influenzae* type b disease.  
 11 Following two doses of ActHIB vaccine given at two-month intervals, 89% of these children  
 12 (mean age 11 months) had anti-PRP antibody titers of  $\geq 1.0$  mcg/mL. This is comparable to anti-  
 13 PRP antibody levels demonstrated in normal children of similar age following two doses of  
 14 ActHIB vaccine. (18)

15

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1 **15 REFERENCES**

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- 14 18 Kaplan SL, et al. Immunogenicity of *Haemophilus influenzae* type b polysaccharide-tetanus  
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- 18
- 19

1 **16 HOW SUPPLIED/STORAGE AND HANDLING**

2

3 **16.1 How Supplied**

4 Single-dose, lyophilized vaccine vial (NDC 49281-547-58) packaged with single-dose diluent vial  
5 (NDC 49281-546-58). Supplied as package of 5 vials each (NDC 49281-545-03).

6

7 The vial stoppers for ActHIB vaccine and diluent are not made with natural rubber latex.

8 **16.2 Storage and Handling**

9 Store lyophilized ActHIB vaccine packaged with saline diluent (0.4% Sodium Chloride) at 2° to  
10 8°C (35° to 46°F). DO NOT FREEZE.

11

12 **17 PATIENT COUNSELING INFORMATION**

13

14 Vaccine Information Statements are required by the National Childhood Vaccine Injury Act of  
15 1986 to be given prior to immunization to the patient, parent, or guardian.

16

17 Inform the patients, parents, or guardians about the potential benefits and risks of the vaccine and  
18 importance of completing the immunization series unless a contraindication to further  
19 immunization exists. In addition to this, parents and guardian must be informed about the  
20 potential for adverse reactions that have been temporarily associated with the administration of  
21 ActHIB vaccine or other vaccines containing similar ingredients. Prior to administration of  
22 ActHIB vaccine healthcare providers should ask parents or guardians about the recent health  
23 status of the infant or child to be immunized. As part of the child's immunization record, the date,

1 lot number, and manufacturer of the vaccine administered should be recorded. (7) (8) (19)  
2 Vaccine recipients and guardians must report any adverse reactions upon administration of the  
3 vaccine to their healthcare provider and/or to the Vaccine Adverse Event Reporting System  
4 (VAERS).

5

6

7 ActHIB is a registered trademark of Sanofi Pasteur Inc.

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Product information

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as of April 2016.

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12 Manufactured by:

13 **Sanofi Pasteur SA**

14 Marcy L'Etoile France

15

16 Distributed by:

17 **Sanofi Pasteur Inc.**

18 Swiftwater PA 18370 USA

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