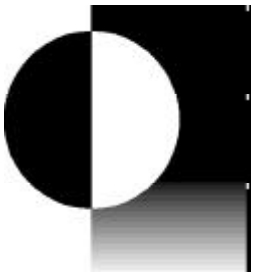
HAEMOPHILUS b CONJUGATE VACCINE (TETANUS PROTEIN - CONJUGATE)



Act-HIB®

DESCRIPTION

Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) (PRP-T) is a lyophilized vaccine of purified polyribose ribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b, covalently bound to tetanus protein. Each single dose of 0.5 mL after reconstitution contains 10 μg of purified capsular polysaccharide covalently bound to 20 μg of tetanus protein.

Act-HIB® reconstituted with Diluent:

The diluent for reconstitution is a 0.4% saline solution. After reconstitution the vaccine appears clear and colourless and does not contain a preservative.

Act-HIB® reconstituted with Aventis Pasteur Limited's QUADRACEL™:

After reconstitution, the vaccine appears cloudy and uniform. From the QUADRACEL™, Component Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed Combined with Inactivated Poliomyelitis Vaccine, the solution contains 0.6% ± 0.1% 2-phenoxyethanol as preservative and trace amounts of polymyxin B and neomycin may be present from the cell growth medium.

Act-HIB® reconstituted with Aventis Pasteur Limited's TRIPACEL™:

After reconstitution, the vaccine appears cloudy and uniform. From the TRIPACEL™, Component Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed, the solution contains 0.6% ± 0.1% 2-phenoxyethanol as preservative.

CLINICAL PHARMACOLOGY

Clinical Data (PRP-T)

Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) (PRP-T) has been administered during clinical trials to over 110,000 infants and children in Canada, the United States, Finland, France, Chile, Israel, and the United Kingdom using local immunization schedules,[1,2] and has been used widely in immunization programmes.

In clinical trials where 921 infants were given the vaccine at 2, 4 and 6 months, a titre of at least 0.15 μg/mL was achieved after dose 3 in 99% and a titre of at least 1.00 μg/mL in 93%. The weighted GMT achieved was 7.0 μg/mL (95% confidence limits are 3.4 - 14.2 μg/mL). Protective levels of anti-PRP developed after the second dose in 92.8% of these infants.[1]

Two clinical trials supported by the U.S. National Institutes of Health (NIH) compared the anti-PRP response of four Hib conjugate vaccines in a racially mixed population of infants. In these studies, infants were immunized with Hib conjugate vaccines at 2, 4 and 6 months of age (see Tables 1 and 2).[1,3] Aventis Pasteur Inc.'s whole-cell DPT vaccine was given concomitantly, at a separate site.[3]

TABLE 1[1,3]

ANTI-PRP ANTIBODY RESPONSES IN 2-MONTH-OLD INFANTS

NIH TRIAL IN TENNESSEE

VACCINE	N*	GEOMETRIC MEAN TITRE (GMT) (μg/mL)			POST THIRD IMMUNIZATION % >1.0 μg/mL
		Pre Immunization	Post Second Immunization	Post Third Immunization	
PRP-T†	65	0.10	0.30	3.64	83%
PRP-D§	62	0.07	0.08	0.28	29%
PRP-OMP¶	64	0.11	0.84	1.14	55%
HbOC‡	61	0.07	0.13	3.08	75%

TABLE 2[1]

ANTI-PRP ANTIBODY RESPONSES IN 2-MONTH-OLD INFANTS

NIH TRIAL IN MINNESOTA AND TEXAS

VACCINE	N*	GEOMETRIC MEAN TITRE (GMT) (μg/mL)			POST THIRD IMMUNIZATION % >1.0 μg/mL
		Pre Immunization	Post Second Immunization	Post Third Immunization	
PRP-T†	106	0.23	1.14**	6.64	98%
PRP-OMP¶	103	0.17	4.6***	6.48	88%
HbOC‡	99	0.16	0.46	6.83	93%

* N - Number of children

** P = 0.0001 for PRP-T vs HbOC

*** P = 0.0001 for PRP-OMP vs PRP-T, and for PRP-OMP vs HbOC

† Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate)

§ Haemophilus b Conjugate Vaccine (Diphtheria Toxoid - Conjugate)

¶ Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)

‡ Haemophilus b Conjugate Vaccine (Diphtheria CRM_{197} Protein Conjugate)

Multi-centre trials in the United States have evaluated a single dose of Act-HIB® in 12-15, 18, and 17-24 month-old children. In this age group, a single dose of Act-HIB® produced an anti-PRP response which was comparable to that seen after three doses were administered in infants.[1]

Following three doses of Act-HIB® at 6 weeks, four and six months of age, 81% of native Alaskan infants showed an anti-PRP titre of ≥1.0 μg/mL with a GMT of 4.17 μg/mL.[1]

In clinical trials conducted in England and France, infants received 3 doses of Act-HIB® at one month intervals. Anti-PRP responses were comparable to those trials where 2-month intervals were used.[1]

Clinical Data – Act-HIB® Reconstituted with QUADRACELä

In clinical trials conducted in Canada, 215 infants received 3 doses of either Act-HIB® reconstituted with QUADRACEL™ or the same vaccines administered simultaneously at separate sites at 2, 4 and 6 months of age. An additional 186 18-month old children received a single dose of either Act-HIB® reconstituted with QUADRACEL™ or the same vaccines administered simultaneously at separate sites. With the exception of tetanus, no differences were found in immunogenicity between the two methods of immunization. Tetanus antitoxin levels were lower in the combined vaccine groups, but all children had protective levels (≥0.01 EU/mL). Following the 18-month dose, all children had tetanus antitoxin levels ≥0.10 EU/mL and all but one had diphtheria antitoxin levels ≥0.10 EU/mL. Anti-PRP responses were comparable. All children were protected against polio. Pertussis responses were not affected by method of administration.

Clinical Data – Act-HIB® Reconstituted with TRIPACELä

In a clinical trial conducted in Canada, 17-19 month old children previously immunized with TRIPACEL™ ($CP_{10/5/5/3}$DT) at 2, 4 and 6 months of age received either a single injection of TRIPACEL™ used to reconstitute Act-HIB® (n=33), or separate injections of TRIPACEL™ and Act-HIB® reconstituted with diluent at the same visit (n=33). All subjects received OPV at the same visit. There were no differences between the study groups for tetanus and diphtheria antitoxin levels or anti-PRP antibody, with all participants achieving tetanus and diphtheria antitoxin levels of >1.0 IU/mL, and anti-PRP antibody levels of >0.15 μg/mL, and 98% of recipients achieving anti-PRP antibody levels of >1.0 μg/mL. There were no significant interactions in the pertussis antibody responses PT, FHA, CHO, 69kDa, fimbriae, or agglutinins. Local and systemic reactions were similar in both study groups.

In a clinical trial conducted in Taiwan, 68 infants received a different formulation of TRIPACEL™ ($CP_{20/20/5/3}$DT) used to reconstitute Act-HIB® and a control group of 67 received the same vaccines administered at separate sites at 2, 4 and 6 months of age. All subjects received OPV at 2, 4, 6 and 18 months. The method of administration did not affect overall serologic responses. All subjects in both groups achieved protective levels for anti-PRP, diphtheria, tetanus and polio. A fourth dose of the same vaccines was given at 18 months of age to 62 children who had received the combined vaccines and 66 who had received separate injections. One hundred percent of participants achieved protective levels for anti-PRP (≥ 1.0 μg/mL), diphtheria (≥ 0.1 IU/mL) and tetanus (≥ 0.1 EU/mL) antitoxin. There was no difference in pertussis serology between the groups. Polio antibody levels were not measured.

Table 3

Summary of Anti-PRP Responses with Various Diluents[1]

Anti-PRP (Post 3rd Dose)

	n	≥0.15 μg/mL	≥1.0 μg/mL	GMT μg/mL
Act-HIB® + DPT* combined	209	97.6%	88.1%	4.44
Act-HIB® + DPT* separate	213	98.6%	87.9%	4.06
Act-HIB® + DPT Polio** combined	211	93.8%	71.6%	2.04
Act-HIB® + DPT Polio** separate	211	98.1%	78.7%	2.76
Act-HIB® + Diluent (saline)	65	99.0%	83.0%	3.64
Act-HIB® + QUADRACEL™ combined	107	99.1%	84.9%	5.04
Act-HIB® + QUADRACEL™ separate	108	100.0%	88.9%	3.83
Act-HIB® + TRIPACEL™ ($CP_{20/20/5/3}$DT) combined	64	100.0%	96.3%	11.80
Act-HIB® + TRIPACEL™ ($CP_{20/20/5/3}$DT) separate	67	100.0%	98.5%	13.00

*whole-cell DPT
**whole-cell DPT Polio

INDICATIONS AND USAGE

1. **Routine**: Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) is indicated for the routine immunization of all children between **2 and 59 months** of age. In infants, three injections are to be given intramuscularly at **2, 4, and 6 months** of age, followed by a booster at **18* months** of age.

2. a) Infants starting their primary immunization series between the age of **3 and 6 months** should receive three doses at two month intervals with a booster dose at **18* months** of age. (While an interval of 2 months between doses is recommended, an interval as short as 1 month is acceptable.)

   b) For infants between the age of **7 and 11 months**, two doses should be given at an interval of two months, followed by a booster at **18* months** of age.

   c) Children between **12 and 14 months** of age who have not previously received any *Haemophilus* b vaccine should receive one dose of the vaccine followed by a booster at or after **18 months*** of age.

   d) Unvaccinated children between **15 and 59 months** of age should receive a single dose of vaccine.

   * The booster dose may be given as early as 15 months of age provided that at least 2 months have elapsed since the previous dose.

3. Older children or adults with chronic conditions associated with increased risk of invasive Hib disease such as persons with splenic dysfunction (eg, sickle cell disease, asplenia), antibody deficiency, HIV infection or certain malignancies may be immunized with a single dose of the vaccine.[5]

4. Aventis Pasteur Limited's QUADRACEL™ may be used for the reconstitution of lyophilized Act-HIB® in place of the saline diluent. This provides an efficient means of administering routine immunization against diphtheria, tetanus, pertussis, poliomyelitis and *Haemophilus influenzae* type b in a single injection at a single visit.

5. Aventis Pasteur Limited's TRIPACEL™ may be used for the reconstitution of lyophilized Act-HIB® in place of the saline diluent. This provides an efficient means of administering routine immunization against diphtheria, tetanus, pertussis, poliomyelitis and *Haemophilus influenzae* type b in a single injection at a single visit.

6. Act-HIB® may be administered simultaneously with whole-cell DPT, DT, whole-cell DPT Polio, IPV, QUADRACEL™, or TRIPACEL™ at separate sites with separate syringes and OPV.

   Act-HIB® may also be given simultaneously with MMR at separate sites with separate syringes. This is based on data for MMR and Act-HIB® alone. Because simultaneous administration of common childhood vaccines is not known to affect the efficacy or safety of any of the routine recommended childhood vaccines, if return of a vaccine recipient for further immunization is doubtful, simultaneous administration of all vaccines appropriate for age and previous vaccination status (including MMR, hepatitis B vaccine) at separate sites with separate syringes is indicated.[6,7]

7. Data on whether vaccination prevents acquisition and carriage of Hib are still limited. Thus, rifampin or other appropriate chemoprophylaxis should be used, in accordance with the usual recommendations[6], for families and persons in day-care centres in which a case of invasive Hib disease has occurred and in which there are one or more contacts less than 48 months of age who have not been fully vaccinated against Hib.[5]

Currently, Haemophilus b conjugate vaccines are not recommended for infants younger than 2 months of age.

CONTRAINDICATIONS

General

Immunization with Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) should be deferred in the presence of any acute illness, including febrile illness to avoid superimposing adverse effects from the vaccine on the underlying illness or mistakenly attributing to the vaccine a manifestation of the underlying illness. A minor afebrile illness such as mild upper respiratory infection is not usually reason to defer immunization.[8]

Absolute Contraindications

Allergy to any component of Act-HIB® (see components listed in DESCRIPTION), including tetanus protein, or an allergic or anaphylactic reaction to a previous dose of Act-HIB® are contraindications to vaccination. When Act-HIB® is reconstituted with Aventis Pasteur Limited's TRIPACEL™ or QUADRACEL™ the contraindications for TRPACEL™ or QUADRACEL™ must also be considered.

Elective immunization of individuals over 6 months of age should be deferred during an outbreak of poliomyelitis because of the risk of provocation paralysis.[9,10,11]

WARNINGS

Intramuscular injections should be given with care in persons suffering from coagulation disorders or on anticoagulant therapy because of the risk of hemorrhage.[8]

If Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) is used in persons with malignancies, persons receiving immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, or persons who are otherwise immunocompromised (including HIV infected individuals, transplant recipients, and persons suffering from autoimmune disorders), the expected immune response may not be obtained.

Corticosteroid therapy can result in immunosuppression although the exact dose and duration of therapy required to suppress the immune system is not well defined. Persons treated with high doses of systemic steroids, eg, ≥2 mg/kg per day of prednisone orally for more than 2 weeks, should be considered to have a compromised immune system.[8]

As with any vaccine, immunization with Act-HIB® may not protect 100% of susceptible individuals.

Capsular polysaccharide antigen can be detected in the urine of vaccinees for up to 2 weeks following immunization with conjugate vaccines. This phenomenon should not be confused with invasive Hib infections.[5]

PRECAUTIONS

General

The possibility of allergic reactions in individuals sensitive to components of the vaccine should be evaluated. Epinephrine Hydrochloride Solution (1:1000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.[8] When Act-HIB® is reconstituted with Aventis Pasteur Limited's TRIPACEL™ or QUADRACEL™, the possibility of allergic reactions to the components of these vaccines must also be evaluated. Health care providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management.[12,6]

Before administration of any vaccine, all appropriate precautions should be taken to prevent adverse reactions. This includes a review of the patient's history with respect to possible hypersensitivity to the vaccine or similar vaccine, determination of previous immunization history, and the presence of any contraindications to immunization, current health status, and a current knowledge of the literature concerning the use of the vaccine under consideration.

Special care should be taken to ensure that the product is not injected into a blood vessel.

Caution

A separate sterile needle and syringe, or a sterile disposable unit, must be used for each individual patient to prevent the transmission of infectious agents.

There have been case reports of transmission of HIV and hepatitis by failure to observe scrupulously sterile technique.

Needles should not be recapped and should be disposed of properly.

Before administration of Act-HIB®, health-care personnel should inform the parent or guardian or the patient to be immunized of the benefits and risks of immunization, inquire about the recent health status of the patient and comply with any local requirements with respect to information to be provided to the patient before immunization.

Act-HIB® may be of benefit in preventing the occurrence of secondary cases. However, epidemiological studies have not been done and rifampin or other appropriate prophylaxis is still recommended. Because the vaccine will not protect against non-typeable strains of *H. influenzae* which cause recurrent upper respiratory disease, otitis media and sinusitis, the vaccine is not recommended for these conditions.

ALTHOUGH SOME IMMUNE RESPONSE TO THE TETANUS PROTEIN COMPONENT MAY OCCUR, IMMUNIZATION WITH THIS VACCINE DOES NOT SUBSTITUTE FOR ROUTINE TETANUS IMMUNIZATION. Individuals who have received multiple doses of products containing tetanus toxoid show no differences in reaction rates when immunized with this vaccine.

Pregnancy

Animal reproduction studies have not been conducted with Act-HIB®. It is also not known whether Act-HIB® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Act-HIB® is not recommended for use in pregnant women.

No evaluation of Act-HIB® has been made with respect to its potential for carcinogenesis or mutagenesis.

Human Immunodeficiency Virus (HIV) Infected Persons

Hiv-infected individuals, both asymptomatic and symptomatic, should be immunized with DPT (Diphtheria, Pertussis, and Tetanus) and Act-HIB® vaccine according to standard schedules.[8]

ADVERSE REACTIONS

Local reactions: Pain, redness, swelling or induration are seen in 5-30% of vaccinees. It is generally early, transient, and of moderate intensity. There have been rare cases of edematous reactions of the lower extremities reported. These consist of edema with cyanosis or transient purpura which appears within soon after immunization and resolves rapidly and spontaneously. There have been no accompanying cardiorespiratory signs or symptoms. These reactions have been reported mainly when Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) is administered concurrently with another vaccine.[1]

Systemic reactions including fever, irritability, drowsiness, prolonged or abnormal crying, anorexia and vomiting have occurred after immunization with Act-HIB® in conjunction with whole-cell DPT. The rates of reactions observed were generally comparable to those usually reported following whole-cell DPT with the exception that there were slightly more febrile reactions reported among PRP-T recipients within 6-24 hours of vaccination. Table 4 shows systemic reactions reported in a controlled clinical trial.[1]

Table 4: Systemic Reactions (%) Within 24 Hours of Vaccination

GROUP	FIRST DOSE		SECOND DOSE		THIRD DOSE	
	PRP-T and DPT**	DPT	PRP-T and DPT**	DPT	PRP-T and DPT**	DPT
ANY SYSTEMIC REACTIONS	77.8	81.8	87.7	75.0	76.5	68.8
FEVER 38°C-38.9°C	27.7	17.5	27.1*	6.5*	16.4	12.1
>39°C	4.1	0.0	2.9	1.6	1.5	3.0
IRRITABILITY	51.8	57.1	47.7	51.9	41.7	41.6
DROWSINESS	43.2	41.6	44.4	28.6	33.3	26.0
LOSS OF APPETITE	8.6	15.6	13.6	15.6	21.2	11.7
VOMITING	3.7	3.9	0.0	0.0	3.7	3.9
DIARRHEA	0.0	1.3	2.5	6.5	6.2	6.5

* P>0.001

** PRP-T Vaccine and whole-cell DPT Vaccine administered at two different sites

Act-HIB® reconstituted with QUADRACELä

In clinical trials conducted in Canada, 215 infants received 3 doses of either Act-HIB® reconstituted with QUADRACEL™ or the same vaccines administered simultaneously at separate sites at 2, 4 and 6 months of age. An additional 186 18-month old children received a single dose of either Act-HIB® reconstituted with QUADRACEL™ or the same vaccines administered simultaneously at separate sites. The rates of local and systemic reactions for the combination of Act-HIB® and QUADRACEL™ were consistently lower than for the combination of Act-HIB® and whole-cell DPT-Polio Adsorbed (PENTA1). The incidence of local reactions at the QUADRACEL™ site was lower when the vaccines are given separately, but severe local reactions are uncommon (<6% for any dose). Systemic reactions were comparable between the two groups. No hypotonic-hyporesponsive episodes following QUADRACEL™ and Act-HIB® administration were reported during these trials. There were three reports of febrile seizures (6 days to 1 month following immunization with QUADRACEL™ and Act-HIB®), all attributed to intercurrent febrile illness.

Act-HIB® reconstituted with TRIPACEL™

In a clinical trial conducted in Canada, 17-19 month old children previously immunized with TRIPACEL™ ($CP_{10/5/5/3}$DT) at 2, 4 and 6 months of age received either a single injection of TRIPACEL™ used to reconstitute Act-HIB® (n=33), or separate injections of TRIPACEL™ and Act-HIB® reconstituted with diluent at the same visit (n=33). All subjects received OPV at the same visit. There was no significant difference in rates of local or systemic reactions. No serious adverse events were observed during this study.

In a clinical trial conducted in Taiwan, 68 infants received a different formulation of TRIPACEL™ ($CP_{20/20/5/3}$DT) used to reconstitute Act-HIB® and a control group of 67 received the same vaccines administered at separate sites at 2, 4 and 6 months of age. A fourth dose of the same vaccines was given at 18 months of age to 62 children who had received the combined vaccines and 66 who had received separate injections. No consistent differences in reaction rates were seen between the two methods of administration. Reaction rates were low in both vaccine groups; local reactions tended to be mild or moderate and systemic reactions tended to be mild. No serious adverse events were observed during this study.

Rare cases of allergic reactions including urticaria, pruritus, and facial and laryngeal edema have been reported.

Physicians should be aware that recipients of *Haemophilus* b vaccine are not protected against Hib disease in the week after vaccination, before the onset of the protective effects of the vaccine.

Other adverse events reported with administration of other *Haemophilus* b conjugate vaccines include urticaria, seizures, rash, renal failure and Guillain-Barré syndrome (GBS). A cause and effect relationship among any of these events and the vaccination has not been established.[1]

As with any vaccine, there is the possibility that broad use of the vaccine could reveal rare adverse reactions not observed in clinical trials. A temporal association of neurological disorders (including encephalopathy, with or without permanent brain damage) and/or intellectual impairement has been reported following the parenteral injection of other biological products and should always be carefully considered when an immunization is indicated.

Physicians should be familiar with the adverse reactions associated with whatever vaccine is used to reconstitute Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) and read carefully the direction leaflet which accompanies each such vaccine.

Physicians, nurses and pharmacists should report any adverse occurrences temporally related to the administration of the product in accordance with local requirements and to the Medical Director, Aventis Pasteur Limited, 1755 Steeles Avenue West, Toronto, Ontario, Canada M2R 3T4.

DOSAGE AND ADMINISTRATION

Parenteral biological products should be inspected visually for extraneous particulate matter and/or discolouration before administration whenever solution and container permit. If these conditions exist, the product should not be administered.

This vaccine is indicated for routine immunization against invasive disease caused by *Haemophilus influenzae* type b in infants and children starting at 2 months of age (See INDICATIONS). Each dose is a single injection of 0.5 mL given intramuscularly.

Reconstitution of Freeze-Dried Product and Withdrawal from Rubber-Stoppered Vial.

Reconstitute the vaccine using only the diluent supplied, Aventis Pasteur Limited's TRIPACEL™ or QUADRACEL™. The use of any other vaccine to reconstitute Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) is not recommended.

DO NOT REMOVE THE RUBBER STOPPER FROM THE VIAL.

Apply a **sterile** piece of cotton moistened with a suitable antiseptic to the surface of the rubber stopper of the vial of vaccine. Withdraw the diluent into a syringe. Holding the plunger of the syringe containing the diluent steady, pierce the centre of the rubber stopper in the vial and **slowly** inject the 0.5 mL of diluent into the freeze-dried vaccine. Do not try to force all of the diluent into the vial at once as this will create pressure. It is necessary to allow air to escape gradually into the syringe by intermittently aspirating air from the vial while injecting the diluent into the vial. Do not remove the needle from the stopper until the required volume of diluent has been injected. Shake the vial gently until a clear, colourless solution results. **Avoid foaming** since this will prevent withdrawal of the proper dose. Withdraw the entire contents of the reconstituted vaccine into the syringe and inject the total volume (about 0.5 mL). Aseptic technique must be used for withdrawal of each dose. (see PRECAUTIONS)

When Aventis Pasteur Limited's TRIPACEL™ or QUADRACEL™ is used for the reconstitution of Act-HIB®, SHAKE THE SINGLE DOSE AMPOULE OR VIAL WELL to distribute uniformly the suspension before withdrawing entire

contents (about 0.5 mL). Before withdrawing the contents from an ampoule, tap the container first to ensure that all the vaccine is in the lower portion. Once the ampoule has been opened, any of its contents not used immediately should be discarded. Before withdrawing the contents from a rubber-stoppered vial, do not remove either the rubber stopper or the metal seal holding it in place. Inject all the TRIPACEL™ or QUADRACEL™ into the vial of Act-HIB® vaccine. Swirl the vial until a cloudy, uniform suspension results. Avoid foaming since this will prevent withdrawal of the proper dose. Use a sterile needle and syringe to withdraw the entire contents for one dose.

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

Administer the vaccine **intramuscularly**. The preferred site is into the anterolateral aspect of the mid-thigh (vastus lateralis muscle) or into the deltoid muscle.

In children >1 year of age, the deltoid is the preferred site since use of the anterolateral thigh results in frequent complaints of limping due to muscle pain.[13]

After insertion of the needle, aspirate to ensure that the needle has not entered a blood vessel.

DO NOT INJECT INTRAVENOUSLY.

Each person who is immunized should be given a permanent personal immunization record. In addition, it is essential that the physician or nurse record the immunization history in the permanent medical record of each patient. This permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

STORAGE

Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) should be stored between 2° and 8°C (35° and 46°F). DO NOT FREEZE. Product which has been exposed to freezing should not be used.

The vaccine should be used immediately after reconstitution.

Do not use after the expiration date.

HOW SUPPLIED

Act-HIB® - Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) is supplied in packages containing five single dose vials of Act-HIB® and five x 0.5 mL (single dose) ampoules of Aventis Pasteur Limited's DILUENT, 0.4% Saline for reconstitution of Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) Act-HIB®.

Act-HIB® is also supplied in packages containing five single dose vials of Act-HIB® and five x 0.5 mL (single dose) ampoules of Aventis Pasteur Limited's QUADRACEL™ to be used for reconstitution in place of the diluent and sold under the tradename PENTACEL™ .

Act-HIB® is also supplied in packages containing five single dose vials of Act-HIB® and five x 0.5 mL (single dose) vials of Aventis Pasteur Limited's TRIPACEL™ to be used for reconstitution in place of the diluent and sold under the tradename ACTACEL™ .

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Product information as of July 1998.

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Aventis Pasteur

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