ACTACEL™

Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) reconstituted with Component Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed

PHARMACEUTICAL FORM

Suspension for injection, obtained by reconstitution of one 1-dose vial of freeze-dried Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) with one 1-dose vial of Component Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed for administration by intramuscular route.

COMPOSITION

1 dose = about 0.5 mL.

Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) (lyophilisate) composition for one immunizing dose after reconstitution:

Haemophilus influenzae type b polysaccharide conjugated to 20 µg of tetanus protein	10 µg
TRIS (Trometamol)	0.6 mg
Sucrose	42.5 mg

Component Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed (suspension for injection) composition for one immunizing dose:

Active ingredients:	
pertussis toxoid (PT)	10 µg
filamentous haemagglutinin (FHA)	5 µg
fimbriae (AGG 2 + 3)	5 µg
pertactin (69kDa protein)	3 µg
diphtheria toxoid	≥30 IU (2.0 units/mL)
tetanus toxoid	≥40 IU (2.0 units/mL)
Other ingredients:	
aluminum phosphate adjuvant (aluminum)	1.5 mg (0.33 mg)
2-phenoxyethanol (preservative)	3.4 mg (0.6% ± 0.1% w/v)
water for injection	ad 0.5 mL

PHARMACEUTICAL CLASSIFICATION

Vaccine, for administration by intramuscular route. Special care should be taken to ensure that the product is not injected into a blood vessel.

INDICATIONS

Primary vaccination of infants, at or above the age of two months and as a booster in children up to their 7th birthday against diphtheria, tetanus, pertussis and invasive *Haemophilus influenzae* type b infection.

As a guide: Primary immunization is begun at the age of 2 months at the earliest and comprises 3 doses, at intervals of one or two months followed by a booster dose administered one year after the third dose.

CONTRAINDICATIONS

Allergy to any component of this vaccine (see components listed in Composition) or an allergic or anaphylactic reaction to a previous dose of this vaccine are contraindications to vaccination.

Vaccination should be postponed in cases of acute illness, including febrile illness. A minor illness such as a mild upper respiratory infection is not usually a reason to defer immunization.

Should not be given to children after their seventh birthday or to adolescents or adults because of the quantity of diphtheria toxoid.

SPECIAL WARNINGS AND PRECAUTIONS

Although anaphylaxis is rare, facilities for its management must always be available during vaccination. Epinephrine Hydrochloride solution (1:1,000) and other appropriate agents should be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.

Deferral

Deferral of the pertussis component of ACTACEL™ should be considered in children with a progressive, evolving, or unstable neurologic condition (including seizures) because administration of the pertussis component may coincide with the onset of overt manifestations of such disorders and result in confusion about causation. It is prudent to delay initiation of immunization with pertussis vaccine until further observation and study have clarified the child's neurologic status. In addition, the effect of treatment, if any, can be assessed. Immunization with ACTACEL™ should be reinstituted when the condition has resolved, been corrected or controlled.

Elective immunization of individuals over 6 months of age should be deferred during an outbreak of poliomyelitis.

Relative Contraindications

Hypotonic-hyporesponsive episodes within 48 hours following previous immunization with a pertussis-containing vaccine requires consideration of whether further doses of ACTACEL™ should be given.

It is possible that children with immune deficiency may not achieve full immunity.

Human Immunodeficiency Virus (HIV) Infected Persons

HIV-infected individuals, both asymptomatic and symptomatic, should be immunized against diphtheria, pertussis, tetanus, poliomyelitis and invasive Hib disease according to standard schedules.

As with any vaccine, immunization with ACTACEL™ may not protect 100% of susceptible individuals.

Use in Pregnancy

Not relevant

Interactions with Other Drugs

If ACTACEL™ is used in persons with malignancies, receiving immunosuppressive therapies, including corticosteroids, irradiation, antimetabolites, alkylating agents, cytotoxic drugs, or who are otherwise immunocompromised (including HIV-infected individuals), the expected immune response may not be obtained.

The vaccine may be administered concurrently with inactivated polio vaccine (IPV) and oral polio vaccine. If the vaccine is administered together with IPV, a separate syringe and different injection site must be used.

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.

INSTRUCTIONS FOR USE

Reconstitute the 1-dose vial of Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) lyophilisate with the 1-dose vial of Component Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed suspension.

Shake the single-dose vial of Component Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed well to uniformly distribute the suspension before withdrawing the entire contents (about 0.5 mL). 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 Component Pertussis Vaccine Combined with Diphtheria and Tetanus Toxoids Adsorbed into the vial of Haemophilus b Conjugate Vaccine (Tetanus Protein - Conjugate) 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.

Must not be mixed with other vaccines in the same syringe.

POSOLOGY

1 dose = about 0.5 mL

Always to be administered in accordance with the prescription of the doctor.

As a guide: Primary immunization is begun at the age of 2 months at the earliest and comprises 3 doses, at intervals of one or two months followed by a booster dose administered one year after the third dose.

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

Do not inject by the intravascular route.

ADVERSE EFFECTS

The most frequent reactions include redness and tenderness at the injection site; irritability and slight fever. These symptoms usually occur within the first 24 hours after vaccination and may continue for 24-48 hours.

Common (>1/100)	Systemic:	Fever, irritability, inconsolable crying, drowsiness, decreased feeding.
	Local:	Redness, tenderness, swelling at the vaccination site.
Less common	Systemic:	Unusual high pitched crying, vomiting, pallor, listlessness.
Uncommon (<1/1,000)	Systemic:	Febrile convulsions, hypotonic-hyporesponsive episodes*, high fever (>40.5°C).
	Local:	Granuloma or sterile abscess at the vaccination site. Edema of lower extremities with cyanosis or transient purpura.

* Hypotonic-hyporesponsive episodes [infants appear pale, hypotonic (limp) and unresponsive to parents] have not to date been associated with any permanent sequelae.

Very Rare (<1/10,000)	The following have been reported following administration of tetanus and/or diphtheria toxoid and/or pertussis-containing vaccines:
	Systemic: Anaphylactic reaction, neurologic (peripheral neuropathies, demyelinating diseases; encephalopathy with and without permanent intellectual and/or motor impairment, polyradiculopathies).

PRECAUTIONS FOR USE

KEEP OUT OF REACH OF CHILDREN.

STORAGE AND SHELF LIFE

Store at 2° to 8°C.

Must not be frozen. Vaccine that has been frozen must not be used.

To be used before the expiry date indicated on the packaging.

Product information as of October 1998.

Manufactured by:
Aventis Pasteur Limited
Toronto, Ontario, Canada

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