

February 2011

Dear Health-care Provider:

As one of our valued customers, we would like to inform you that we will be discontinuing the supply of **Tripedia**<sup>®</sup> (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) and **TriHIBit**<sup>®</sup> (Haemophilus b Conjugate Vaccine [Tetanus Toxoid Conjugate]-ActHIB<sup>®</sup> reconstituted with Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed-Tripedia) as we focus our efforts on supporting our other DTaP<sup>a</sup> and Hib<sup>b</sup> products. We anticipate that supplies will last through April 2011. This is subject to change based on fluctuations in demand.

We are pleased to continue to offer you a full line of DTaP and Hib products, including **Pentacel**<sup>®</sup> (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate [Tetanus Toxoid Conjugate] Vaccine), **DAPTACEL**<sup>®</sup> (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed), and **ActHIB**<sup>®</sup> (Haemophilus b Conjugate Vaccine [Tetanus Toxoid Conjugate]).

Pentacel is the first and only DTaP-IPV<sup>c</sup>/Hib vaccine:<sup>1</sup>

- As a 4-dose Hib-containing combination vaccine, Pentacel vaccine fits naturally into the primary series at 2, 4, and 6 months of age, with a booster at 15 to 18 months<sup>1,2</sup>
- With 4 doses of Pentacel vaccine, you can help reduce the number of injections during both the primary series and at the crowded toddler visit<sup>2,3</sup>
- A primary pertussis immunization series consists of 4 doses of Pentacel vaccine; therefore, children who have completed the 4-dose series with Pentacel vaccine should receive a fifth dose of DTaP at 4 to 6 years of age<sup>1</sup>

DAPTACEL, a 5-component acellular pertussis vaccine, is approved for all 5 doses of DTaP in children 6 weeks through 6 years of age. It is highly protective against all severities of pertussis.<sup>4</sup>

These products provide the option of using a single-entity DTaP—DAPTACEL vaccine—or a DTaP in combination with IPV and Hib—Pentacel vaccine.

ActHIB vaccine induces a robust immune response that helps protect against invasive Hib disease in infants and toddlers. It has been in continuous supply since launch in 1996, with more than 80 million doses distributed in the United States.<sup>5,6</sup>

This envelope contains additional important information about Pentacel and DAPTACEL vaccines.

We hope the discontinuation of Tripedia and TriHIBit vaccines will not cause any inconvenience in your practice. If you have questions or require additional information about alternatives to the discontinued vaccines, please contact our customer account representatives at **1-800-VACCINE** (1-800-822-2463).

We look forward to continuing to serve you and your patients.

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## Indications

ActHIB vaccine is indicated for the active immunization of infants and children 2 through 18 months of age for prevention of invasive disease caused by *Haemophilus influenzae* type b.

DAPTACEL vaccine is indicated for active immunization against diphtheria, tetanus, and pertussis as a 5-dose series in infants and children 6 weeks through 6 years of age (prior to seventh birthday).

Pentacel vaccine is indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis, and invasive disease due to *Haemophilus influenzae* type b. Pentacel vaccine is approved for use as a 4-dose series in children 6 weeks through 4 years of age (prior to fifth birthday).

## Safety Information

The most common local and systemic adverse reactions to ActHIB vaccine include injection site erythema, swelling, and tenderness; fever, irritability, drowsiness, and anorexia. Other adverse reactions may occur. ActHIB vaccine is contraindicated in persons with known hypersensitivity to any component of the vaccine. The decision to give ActHIB vaccine should be based on the potential benefits and risks; if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid; or if adverse events have occurred in temporal relation to receipt of tetanus toxoid-containing vaccine. Vaccination with ActHIB vaccine may not protect all individuals.

The most common local and systemic adverse reactions to DAPTACEL vaccine include injection site redness, swelling, and tenderness; fever, irritability, drowsiness, and crying more than usual. Other adverse reactions may occur. DAPTACEL vaccine is contraindicated in persons with any immediate anaphylactic reaction or hypersensitivity to any component of the vaccine. The decision to give DAPTACEL vaccine should be based on the potential benefits and risks; if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid; or if adverse events have occurred in temporal relation to receipt of pertussis-containing vaccine. Encephalopathy within 7 days of administration of a previous dose of a pertussis-containing vaccine or a progressive neurologic disorder is a contraindication. Vaccination with DAPTACEL vaccine may not protect all individuals.

The most common local and systemic adverse reactions to Pentacel vaccine include injection site redness, swelling, and tenderness; fever, fussiness, and crying. Other adverse reactions may occur. Known systemic hypersensitivity reaction to any component of Pentacel vaccine or a life-threatening reaction after previous administration of the vaccine or a vaccine containing the same substances are contraindications to vaccination.

The decision to give Pentacel vaccine should be based on the potential benefits and risks; if Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid; or if adverse events have occurred in temporal relation to receipt of pertussis-containing vaccine. Encephalopathy within 7 days of administration of a previous dose of a pertussis-containing vaccine or a progressive neurologic disorder is a contraindication. Vaccination with Pentacel vaccine may not protect all individuals.

Before administering ActHIB, DAPTACEL, and Pentacel vaccines, please see accompanying full Prescribing Information.

Sincerely,



Julian Ritchey  
Associate Vice President, Marketing, US

<sup>a</sup> DTaP = Diphtheria, tetanus, and acellular pertussis.

<sup>b</sup> Hib = *Haemophilus influenzae* type b.

<sup>c</sup> IPV = Inactivated poliovirus.

ActHIB vaccine is manufactured by Sanofi Pasteur SA and distributed by Sanofi Pasteur Inc.

DAPTACEL vaccine is manufactured by Sanofi Pasteur Limited and distributed by Sanofi Pasteur Inc.

TriHIBit vaccine: ActHIB vaccine combined with Tripedia by reconstitution.

Tripedia vaccine is manufactured and distributed by Sanofi Pasteur Inc.

Pentacel vaccine is manufactured by Sanofi Pasteur Limited and Sanofi Pasteur SA and distributed by Sanofi Pasteur Inc.

**References:** **1.** Pentacel vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.; 2009. **2.** Centers for Disease Control and Prevention. Recommended immunization schedules for persons aged 0 through 18 years—United States, 2010. *MMWR*. 2010;58(51&52):1-4. **3.** Food and Drug Administration. Pentacel<sup>®</sup>: DTaP-IPV/Hib Combined (diphtheria and tetanus toxoids and acellular pertussis adsorbed, inactivated poliovirus and *Haemophilus b* conjugate [tetanus toxoid conjugate] vaccine combined). VRBPAC Briefing Document. <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4275B1-01.pdf>. Accessed December 2, 2010. **4.** Gustaffson L, Hallander HO, Olin P, Reizenstein E, Storsaeter J. A controlled trial of a two-component acellular, a five-component acellular, and a whole-cell pertussis vaccine. *N Engl J Med*. 1996;334:349-355. **5.** ActHIB vaccine [Prescribing Information]. Swiftwater, PA: Sanofi Pasteur Inc.; 2009. **6.** Sanofi Pasteur Inc. Data on file (ActHIB sales by dose), December 2009. MKT18628.