98.5% achieved diphtheria antitoxin levels of ≥1.0 IU/mL after the fourth dose. This Gram-negative coccobacillus produces a variety of biologically active components, though their role in either the pathogenesis of, or immunity to, pertussis has not been clearly defined. After the third dose, 100% (N = 1,037) achieved tetanus antitoxin levels of ≥1.0 IU/mL. In a US study in which children received 4 doses of DAPT ACEL at 2, 4, 6 and 17 months of age, 2 years after the third dose of vaccine. The protective efficacy of DAPT ACEL against pertussis vaccine (N = 2,102); or DT vaccine as placebo (Swedish National Bacteriological Laboratory, N = 2,102) against mild pertussis (~1 day of cough with laboratory confirmation) was 77.9% (95% CI 72.6 to 82.8%) in the active vaccine group vs. 68.6% (95% CI 63.0 to 73.9%) in the placebo group. Compared to the placebo group, children who received 4 doses of DAPT ACEL had significantly higher geometric mean titers (GMTs) to all 4 meningococcal serogroups (D, C, Y, W-135) compared to meningococcal conjugate vaccine (MenB-FHSS), 30 days following the fourth dose of vaccine. GMTs to FHA (hemagglutination inhibition, HI) and PT (complement fixation, CF) were higher for MenB-FHSS compared to 4 doses of DAPT ACEL. In the US study, GMTs to FHA were 176-fold higher for MenB-FHSS than 4 doses of DAPT ACEL. The 95% CI of the geometric mean ratio was not included in the range of 1.000 to 1.050. Pertussis may supervene in the presence of antibody, but the antibodies may be of the total immunoglobulin or of the specific IgG class. As is true for vaccines against other infectious diseases, the presentation of the DT vaccine is not a substitute for medical care. The vaccine antigens in the DT preparation are killed tetanus toxoid and diphtheria toxoid. Vaccine conjugate, IPV, 7-valent pneumococcal conjugate vaccine, and hepatitis B vaccine adsorbed (trivalent). The vial stopper for this product is not made with natural rubber latex. It is not expected that the antibodies present in the pertussis toxoid will interfere in the immune response to the measles, rubella, and varicella antigens or to the varicella-zoster virus vaccine. It is not expected that the antibodies present in the pertussis toxoid will interfere in the immune response to the measles, rubella, and varicella antigens or to the varicella-zoster virus vaccine. The results of prior vaccination are not compromised by administration of this vaccine. The results of prior vaccination are not compromised by administration of this vaccine. The vial stopper for this product is not made with natural rubber latex.
FULL PRESCRIBING INFORMATION:

4.3 Pharmacokinetics: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

4.4 Protein and Peptide Analysis: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

4.5 Residual Solvents: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

4.6 Irritants: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

4.7 Pyrogenicity: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

4.8 Synthesis: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.1 DESCRIPTION: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.2 GUIDELINES FOR RECONSTITUTION AND STORAGE OF INJECTION VIALS

5.2.1 Guidelines for Reconstitution and Storage of Injections Vials

5.2.2 Use of Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, DAPTACEL should be used as the fifth dose of the DTaP series in children who initially received and DTaP vaccines from different manufacturers for successive doses of the DTaP vaccination.

5.3 SIDE EFFECTS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.4 Infants and Children with a History of Previous Seizures: For infants or children with a history of previous seizures, an appropriate antipyretic may be given to prevent fever and subsequent seizures. An antipyretic may be given to prevent fever and subsequent seizures. An antipyretic may be given to prevent fever and subsequent seizures.

5.5 INDICATIONS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.6 DOSAGE: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.7 DOSAGE FORMS AND STRENGTHS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.8 HOW SUPPLIED: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.9 ADMINISTRATION: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.10 REACTIONS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.11 ALLERGIC REACTIONS, INCLUDING ANAPHYLAXIS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.12 IMPROPER USE: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.13 CONTRAINDICATIONS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.15 HEPATO TOXICITY: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

5.16 IMMUNITY: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

6.0 PRECAUTIONS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

7.0 ADVERSE REACTIONS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

8.0 USE IN SPECIFIC POPULATIONS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

9.0 CLINICAL EXPERIENCE: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

10.0 LABORATORY TESTS: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

11.0 CLINICAL STUDIES: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

12.0 IMMUNOLOGICAL STUDIES: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.

13.0 ATTACHMENT: Pentacel® contains two antigens adsorbed onto aluminum phosphate: diphtheria toxoid and tetanus toxoid conjugate. The toxoids are the same as those derived from the respective whole-cell diphtheria and tetanus toxoids in the currently licensed whole-cell DTP vaccine. These antigens are adsorbed separately onto aluminum phosphate.
DAPT ACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**FULL PRESCRIBING INFORMATION:**

DAPT ACEL should be used as the fifth dose of the DT aP series in children who initially received their fourth dose of DTP vaccine at 15-17 months of age or older. It may be used as the fifth dose of the DT aP series in children who initially received their fourth dose of DTP at 6 months of age or older, if the child was not receiving IPV. For children receiving their fifth dose of DAPT ACEL, the minimum interval between the fourth and fifth doses of DAPT ACEL should be at least 28 days. DAPT ACEL should also be used as a fifth dose of the DT aP series in children who initially received their fourth dose of DTP at 6 months of age or older, if the child was not receiving IPV, and who initially received their first dose of DAPT ACEL at 2 months of age or older.

**5.1 Management of Acute Allergic Reactions**

Administration of DAPT ACEL should be discontinued if signs or symptoms of a severe allergic reaction occur following the injection. The injection site should be removed, and appropriate medical assistance should be sought immediately. The injection site should be treated with a cool, wet compress. For administration of DAPT ACEL, the needle should be removed, and the injection site should be treated with a cool, wet compress. If severe reactions occur, the child should be observed for 30 minutes after administration of DAPT ACEL.

**3 DOSAGE FORMS AND STRENGTHS**

DAPT ACEL is a liquid aluminum-adsorbed diphtheria, tetanus and acellular pertussis vaccine. It contains diphtheria toxoid, tetanus toxoid, and pertussis toxoid. The adsorbed diphtheria, tetanus and acellular pertussis components are combined with aluminum hydroxide, aluminum lactate, and aluminum phosphate as adjuvants. The vaccine also contains cattle serum, formalin, residual glutaraldehyde, and residual formaldehyde.

**4 USE IN SPECIFIC POPULATIONS**

**4.1 Pregnancy**

DAPT ACEL is not a vaccine for pregnant women. However, data from the Institute of Medicine indicates that pregnant women who receive DAPT ACEL should be informed of the potential risks of vaccination during pregnancy, including the possibility of adverse events such as fever, irritability, and respiratory infection.

**4.2 Lactation**

DAPT ACEL is not a vaccine for lactating women. However, data from the Institute of Medicine indicates that lactating women who receive DAPT ACEL should be informed of the potential risks of vaccination during lactation, including the possibility of adverse events such as fever, irritability, and respiratory infection.

**5.2 Side Effects**

The most common adverse reactions associated with DAPT ACEL are fever, irritability, and respiratory infection. These reactions are typically mild to moderate in severity and are self-limiting. The reactions are most common in children under 6 months of age and in children who have not been vaccinated with DAPT ACEL previously.

**7.2 Immunosuppressive Treatments**

Drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to DAPT ACEL.

**8 USE IN SPECIFIC POPULATIONS**

**8.2 Lactation**

DAPT ACEL is not a vaccine for lactating women. However, data from the Institute of Medicine indicates that lactating women who receive DAPT ACEL should be informed of the potential risks of vaccination during lactation, including the possibility of adverse events such as fever, irritability, and respiratory infection.

**9.2 Dose Selection**

The recommended dose of DAPT ACEL is 0.5 mL. The dose should be administered intramuscularly into the upper arm or buttock muscle. The injection site should be deep and firm, and the needle should be removed after injection. The injection site should be treated with a cool, wet compress. If severe reactions occur, the child should be observed for 30 minutes after administration of DAPT ACEL.

**10.6 Use in Patients with a History of Immediate Allergic Reactions to Pertussis Vaccine**

Individuals with a documented history of immediate allergic reactions to pertussis vaccine should not receive DAPT ACEL. DAPT ACEL should be used as the fifth dose of the DT aP series in children who initially received their fourth dose of DTP vaccine at 15-17 months of age or older. It may be used as the fifth dose of the DT aP series in children who initially received their fourth dose of DTP at 6 months of age or older, if the child was not receiving IPV.

**13 OTHER INFORMATION**

DAPTACEL® is a trademark of Sanofi Pasteur, Inc. Sanofi Pasteur SA, 29 Av. Porte d’Auteuil, 75116 Paris, France. The conditions and protocols of the vaccine trial described in this report were approved by the local Institutional Review Board and conformed to the ethical principles of the Declaration of Helsinki. The data were analyzed in a blinded manner. The study was sponsored by Sanofi Pasteur, Inc. Sanofi Pasteur SA, 29 Av. Porte d’Auteuil, 75116 Paris, France.

**14 ALCOHOL, NARCOTICS, OTHER DRUGS AND NON-MEDICALLY NEEDED SUBSTANCES**

The use of alcohol, narcotics, other drugs, and non-medically needed substances should be avoided during and after vaccination with DAPT ACEL.

**16 PATIENT COUNSELING INFORMATION**

The patient counseling information should include a discussion of the potential benefits and risks of vaccination with DAPT ACEL. The patient counseling information should also include a discussion of the potential risks of vaccination during pregnancy and lactation.

**17 REFERENCES**

Data from the Institute of Medicine indicate that vaccination during pregnancy and lactation is not contraindicated. However, data from the Institute of Medicine indicates that vaccination during pregnancy and lactation should be avoided if possible.

**18 PATIENT INSTRUCTIONS**

The patient instructions should include a discussion of the potential benefits and risks of vaccination with DAPT ACEL. The patient instructions should also include a discussion of the potential risks of vaccination during pregnancy and lactation.

**19 REPORTING SUSPECTED ADVERSE REACTIONS**

The reporting of adverse reactions to DAPT ACEL is encouraged. The reporting of adverse reactions to DAPT ACEL should be done to the manufacturer, Sanofi Pasteur, Inc. Sanofi Pasteur SA, 29 Av. Porte d’Auteuil, 75116 Paris, France, or to the appropriate regulatory agency. The reporting of adverse reactions to DAPT ACEL is necessary to monitor the safety of the vaccine.

**20 ADDITIONAL INFORMATION**

Data from the Institute of Medicine indicate that vaccination during pregnancy and lactation is not contraindicated. However, data from the Institute of Medicine indicates that vaccination during pregnancy and lactation should be avoided if possible.

**21 DESCRIPTION**

Each 0.5 mL dose of DAPTACEL® contains 5 mcg residual formaldehyde, <50 ng residual glutaraldehyde and 3.3 mg (0.6% v/v) 2-phenoxyethanol (not as a preservative).

**22 CLINICAL PHARMACOLOGY**

**22.1 Mechanism of Action**

DAPT ACEL is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**22.2 Preclinical Pharmacology**

DAPT ACEL is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**22.3 Clinical Pharmacology**

DAPT ACEL is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**23 CLINICAL TRIALS**

**23.1 Study Design**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**23.2 Efficacy**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**23.3 Safety**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**24 PLACEBO-CONTROLLED CLINICAL TRIALS**

**24.1 Study Design**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**24.2 Efficacy**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**24.3 Safety**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**25 STUDY POPULATION**

**25.1 Description**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**25.2 Enrollment**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**25.3 Study Design**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**25.4 Baseline Characteristics**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**25.5 Randomization and Blinding**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**26 MANUFACTURING PROCESSES**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**27 QUALITY CONTROL**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**28 STABILITY**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**29 MANUFACTURER**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**30 PATIENT COUNSELING INFORMATION**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**31 CLINICAL PHARMACOLOGY**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**32 PLACEBO-CONTROLLED CLINICAL TRIALS**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**33 STUDY POPULATION**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**34 BASELINE CHARACTERISTICS**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**35 RANDOMIZATION AND BLINDING**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**36 MANUFACTURING PROCESSES**

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**38 STABILITY**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.

**39 MANUFACTURER**

DAPTACEL® is a vaccine indicated for active immunization against diphtheria, tetanus and acellular pertussis.
INDICATIONS AND USAGE
FULL PRESCRIBING INFORMATION:
DAPTACEL should be used as the fifth dose of the DTaP series in children who initially received
a previous dose of a pertussis containing vaccine that is not attributable to another identifiable cause
of injection. In older children, the deltoid muscle is usually large enough for injection. The vaccine
should be administered with different syringes and at different injection sites.

Dosage and Administration (2.1)

If any of the following events occur within the specified period after administration of a
vaccine, the site should be observed for at least 1 hour to determine the potential for a more
serious adverse event.

EARLY MILD EVENTS:

Crying
Redness
Tenderness
Local pain
Swelling
Fussiness/Irritability

Mild

Moderate:

Subject cries when site is touched; Severe:

Subject cries when leg or arm is moved.

Moderate:

Interfered with activities, but did not require medical care or
absenteeism; Severe:

Incapacitating, unable to perform usual activities, may have/or
absenteeism.

Table 1: Percentage of Infants from Sweden I Efficacy Trial with Local or Systemic Events

<table>
<thead>
<tr>
<th>Event</th>
<th>DT</th>
<th>DAPTACEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crying</td>
<td>5.2</td>
<td>7.8</td>
</tr>
<tr>
<td>Redness</td>
<td>23.6</td>
<td>25.8</td>
</tr>
<tr>
<td>Tenderness</td>
<td>9.3</td>
<td>10.0</td>
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<tr>
<td>Local pain</td>
<td>3.9</td>
<td>5.6</td>
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<tr>
<td>Swelling</td>
<td>50.6</td>
<td>57.4</td>
</tr>
<tr>
<td>Fever ≥38°C</td>
<td>2.3</td>
<td>4.6</td>
</tr>
<tr>
<td>Interference with</td>
<td>3.5</td>
<td>5.8</td>
</tr>
<tr>
<td>Normal activities</td>
<td>51.4</td>
<td>56.6</td>
</tr>
</tbody>
</table>

The incidence of redness, tenderness and local pain was similar among
infants in the DT and DAPTACEL groups. However, the incidence of swelling
with DAPTACEL at 24 hours was significantly higher than that with DT.

Table 5: Percentage of Children from Six Clinical Trials with Local or Systemic Events

<table>
<thead>
<tr>
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<td>20.0</td>
</tr>
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<td>Normal activities</td>
<td>51.5</td>
<td>56.6</td>
</tr>
</tbody>
</table>

Table 6: Percentage of Children from Six Clinical Trials with Local or Systemic Events

<table>
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<th>DT</th>
<th>DAPTACEL</th>
</tr>
</thead>
<tbody>
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<td>Crying</td>
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The incidence of redness, tenderness and local pain was similar among
infants in the DT and DAPTACEL groups. However, the incidence of swelling
with DAPTACEL at 24 hours was significantly higher than that with DT.
DAPT ACEL has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility. A strain of coccobacillus produces a variety of biologically active components, though their role in either the etiology of diphtheria or tetanus is unknown because there are no established serological correlates of protection for pertussis. When DAPT ACEL and Menactra were administered concomitantly but the clinical significance is unknown. In order to assess the antibody response to the pertussis antigens of DAPT ACEL in the US population, a Canadian study (2.2) was conducted in infants 2 through 5 years of age, DAPT ACEL was administered as follows: concomitantly with IPV (Sanofi Pasteur Canada); Menactra® (Sanofi Pasteur Canada) at 4 and 6 months of age; and DAPT ACEL at 15-16 months of age. (2.1, 2.2)

Multiple sites have been reported following vaccination with DAPT ACEL. (5.3) Syncope (fainting) has been reported following vaccination with DAPT ACEL. (5.3) For infants and children with a history of previous seizures, an antipyretic may be used prior to administration of DAPT ACEL. (4.1) Rates of adverse reactions varied by dose number, with systemic reactions most frequent following doses 1-3 and injection site reactions most frequent following the fourth dose. (6.1)

The five dose immunization series consists of a 0.5 mL intramuscular injection of DAPT ACEL into the gluteal muscle. (2.2) The five dose immunization series should be administered at 2, 4, 6 and 15-20 months of age, and at 4-6 years of age. (2.1, 2.2)

Protection. (4.1) Adverse reactions (e.g., fever) following administration of DAPT ACEL are not expected to interfere in the immune response to the measles, rubella, and varicella antigens or to the other vaccines containing similar components. (5.1) A short-term increase in transaminase levels has been observed following DAPT ACEL. (5.5) Protection against tetanus was sustained for the 2-year follow-up period. (8.2)

This product is for intramuscular use only. The injection site should be rotated for subsequent doses. (5.3) DAPT ACEL should be stored at 2° to 8°C (35° to 46°F). DO NOT FREEZE. Product which has been frozen should not be used. (16)

The five dose immunization series consists of a 0.5 mL intramuscular injection of DAPT ACEL into the gluteal muscle. (2.2) The five dose immunization series should be administered at 2, 4, 6 and 15-20 months of age, and at 4-6 years of age. (2.1, 2.2)

The designates the maximum antibody levels achieved with the specified antigen. (5.5) The five dose immunization series consists of a 0.5 mL intramuscular injection of DAPT ACEL into the gluteal muscle. (2.2) The five dose immunization series should be administered at 2, 4, 6 and 15-20 months of age, and at 4-6 years of age. (2.1, 2.2)

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