## DAPTACEL® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed)

DAPTACEL 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 7<sup>th</sup> birthday).

## IMPORTANT SAFETY INFORMATION FOR DAPTACEL® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed)

DAPTACEL is contraindicated in anyone who has had a severe allergic reaction (e.g., anaphylaxis) after a previous dose of any diphtheria toxoid-, tetanus toxoid-, or pertussis antigen- containing vaccine, or any component of DAPTACEL; has a progressive neurologic disorder; or experienced encephalopathy within 7 days after a previous dose of a pertussis antigen-containing vaccine with no other identifiable cause.

Carefully consider benefits and risks before administering DAPTACEL to persons with a history of: fever  $\geq$ 40.5°C (105°F), hypotonic-hyporesponsive episode or persistent, inconsolable crying lasting  $\geq$ 3 hours within 48 hours after a previous pertussis-containing vaccine; seizures within 3 days after a previous pertussis-containing vaccine.

If Guillain-Barré syndrome or brachial neuritis has occurred within 6 weeks following previous vaccination with a tetanus toxoid-containing vaccine; or if adverse events have occurred in temporal relation to a previous dose of DAPTACEL or receipt of any other tetanus toxoid-, diphtheria toxoid-, or pertussis antigen-containing vaccine, the decision to give DAPTACEL should be based on careful consideration of the potential benefits and risks.

For infants and children with a history of previous seizures, an antipyretic may be administered (in the dosage recommended in its prescribing information) at the time of vaccination with DAPTACEL and for the next 24 hours.

Apnea following intramuscular vaccination has been observed in some infants born prematurely.

Syncope (fainting) has been reported following vaccination with DAPTACEL. Procedures should be in place to avoid injury from fainting.

The most common local and systemic adverse reactions to DAPTACEL include redness, swelling, and tenderness at the injection site; fever, irritability, drowsiness, and abnormal crying. Other adverse reactions may occur. Vaccination with DAPTACEL may not protect all individuals.

Please see full Prescribing Information for Daptacel