

Pentacel® [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine]

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

IMPORTANT SAFETY INFORMATION FOR PENTACEL

Contraindications to vaccination with Pentacel include: a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Pentacel, any ingredient of Pentacel, or any other diphtheria toxoid-, tetanus toxoid-, pertussis antigen-containing vaccine, inactivated poliovirus vaccine, or *Haemophilus influenzae* type b vaccine; encephalopathy within 7 days after a previous dose of a pertussis antigen-containing vaccine with no other identifiable cause; or a progressive neurologic disorder.

Carefully consider benefits and risks before administering Pentacel to persons with a history of: fever $\geq 105^{\circ}\text{F}$, hypotonic-hyporesponsive episode, or persistent, inconsolable crying lasting ≥ 3 hours within 48 hours after a previous pertussis antigen-containing vaccine; seizures within 3 days after a previous pertussis antigen-containing vaccine; or adverse events after a previous dose of Pentacel or receipt of any other tetanus toxoid-, diphtheria toxoid-, or pertussis antigen-containing vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following Pentacel.

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 Pentacel and for the next 24 hours.

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

The most common local and systemic adverse reactions to Pentacel include redness, swelling, and tenderness at the injection site; fever, fussiness, and abnormal crying. Other adverse reactions may occur.

Vaccination with Pentacel may not protect all individuals.

Please see full Prescribing Information for Pentacel ([49281-0510-05](#) and [49281-0511-05](#))