

Pentacel™

Dose # (0.5mL/IM)	Timing of Doses	Comments
1	2 months	Dose 1 may be given as early as 6 weeks of age.
2	4 months	Minimum age for dose 2 is 10 weeks . Minimum interval between dose 1 and 2 is 4 weeks.
3	6 months	Minimum age for dose 3 is 14 weeks . Minimum interval between dose 2 and 3 is 4 weeks.
4	15-18 months	Minimum age for dose 4 is 12 months (determined by DtaP and Hib components). The minimum interval between dose 3 and 4 is 6 months. Note: The minimum interval AND age must be met for the 4 th dose of DtaP or Hib (as Pentacel or any other formulation) to be counted as valid. Maximum age for Pentacel is 4 years, 11 months (less than 5 years of age).



Contraindications

- A severe allergic reaction after a previous dose of Pentacel™ vaccine, any component of the vaccine, or any other tetanus toxoid, diphtheria toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine or *H Influenzae* type b vaccine (Because of uncertainty as to which ingredient of the vaccine caused the allergic reaction, none of the ingredients should be administered).
- Encephalopathy (e.g. coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of a pertussis containing vaccine that is not attributable to another identifiable cause.

Pentacel Indications and Usage:

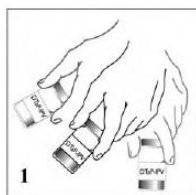
- Combination DTaP/IPV (liquid), and Hib (lyophilized) vaccine.
- Recommended for use in infants at 2, 4, 6 months for the primary doses and 15-18 months for a booster dose.
- Approved for use in children 6 weeks through 4 years of age (prior to 5th birthday).
- Indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to *Haemophilus influenzae* type b.
- May be used when any component of the combination (DTaP-IPV/Hib) is indicated, and if the other components are not contraindicated.
- **Four** doses of Pentacel vaccine constitute a primary immunization course against pertussis.
- **Three** doses of Pentacel vaccine constitute a primary immunization course against diphtheria, tetanus, H influenzae type b invasive disease, and poliomyelitis immunizations.
- Pentacel may be used to complete the first 4 doses of the 5-dose DTaP series and single antigen DTaP vaccine should be used for the 5th dose to complete the series at 4-6 years.
- Can be administered with other vaccines given at the same time.

Please Note

Infants with unstable or undiagnosed neurological disorders should not be immunized with DtaP-containing vaccines until further clarification of the neurological disorder and the impact of treatment has been determined.

- The ACIP recommends that the final dose in the 4-dose IPV series be administered at age ≥ 4 years. If Pentacel vaccine is administered at ages 2, 4, 6 and 15-18 months, an additional booster dose of IPV vaccine should be administered at age 4-6 years, resulting in a 5-dose IPV series.
- Pentacel may be used to complete the vaccination series in infants and children previously vaccinated with one or more doses of Hib conjugate vaccine (either separately administered or in a combination vaccine). If different brands of Hib vaccine are administered to complete the series, 3 primary doses are needed, followed by a booster dose.

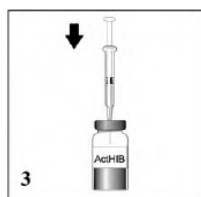
Pentacel Reconstitution:



Step 1: Gently shake the vial containing the DtaP/IPV component.



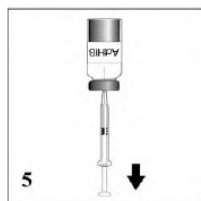
Step 2: Withdraw the entire liquid content of DtaP/IPV.



Step 3: Insert the syringe needle through the stopper of the vial of the lyophilized ActHIB vaccine component and inject the liquid into the vial.



Step 4: Shake the vial thoroughly.



Step 5: After reconstitution, immediately withdraw 0.5mL of Pentacel vaccine and administer intramuscularly. Use **immediately** after reconstitution.

Precautions

- Moderate or severe acute illness with or without fever.
- Fever $\geq 105^\circ\text{F}$, hypotonic-hyporesponsive episode (HHE) or persistent, inconsolable crying lasting ≥ 3 hours within 48 hours after a previous pertussis-containing vaccine.
- Seizures within 3 days after a previous pertussis-containing vaccine.
- Guillain-Barré syndrome within 6 weeks after a previous tetanus toxoid-containing vaccine.
- For infants or children with a history of previous seizures, an appropriate antipyretic may be administered (recommended dosage for age) at the time of vaccination and for the following 24 hours to reduce the possibility of post-vaccination fever.

Adverse Reactions

- **Systemic:** fussiness/irritability, inconsolable crying
- **Local:** injection site tenderness and increased arm circumference

Vaccine Storage and Handling

- Store and transport **both** liquid DtaP/IPV component and lyophilized ActHib component refrigerated at $35\text{-}46^\circ\text{F}$.
- **Do not freeze.**
- Reconstitute the liquid DtaP/IPV component with the lyophilized ActHib component **before** administration.
- Administer **immediately** after reconstitution.