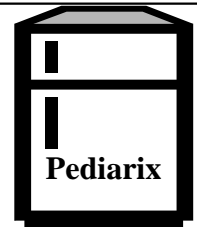


DTaP/IPV/HepB (Pediarix®)

<p>Indications for Use and Schedule</p> <p><u>Approved for:</u></p> <ul style="list-style-type: none"> · Routine schedule 2, 4, 6 months of age · Dose 1, 2, 3 of DTaP; dose 1, 2, 3 of IPV; any dose of Hep B · Ages 6 weeks through 6 years (6 years, 364 days) <p><u>Do not use:</u></p> <ul style="list-style-type: none"> · For the 4th or 5th dose of DTaP or the 4th dose of IPV · For children 7 years of age or older <p><u>Make sure minimum age and minimum intervals are met:</u></p> <ul style="list-style-type: none"> · Minimum age for dose 1 is 6 weeks · Minimum age for dose 3 is 6 months · Minimum intervals: <ul style="list-style-type: none"> - 4 weeks between dose 1 & 2 - 8 weeks between dose 2 & 3 	<p>Vaccine Administration</p> <ul style="list-style-type: none"> · Intramuscular (IM) injection in the deltoid of the arm or anterolateral thigh · 1 inch needle; 22-25 gauge · Professional judgment is appropriate when selecting needle length and site · Can be given with other vaccines, at the same visit <p>Storage and Handling</p> <ul style="list-style-type: none"> · Store in the refrigerator between 35°-46° F (2°-8°C) · Do NOT freeze · Keep in the original box · Shake well before using
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CONTRAINDICATIONS

- An anaphylactic reaction to a prior dose of Pediarix®, DTaP, IPV or Hep B vaccines
- An anaphylactic reaction to a component of DTaP/IPV/Hep B (Pediarix®) including yeast, neomycin or polymyxin B
- Encephalopathy not due to another cause occurring within 7 days after vaccination with a pertussis-containing vaccine
- Progressive neurologic disorder (such as infantile spasms, uncontrolled epilepsy or progressive encephalopathy)

PRECAUTIONS

- Moderate to severe acute illness
- Guillain-Barré syndrome within 6 weeks of a prior vaccine containing tetanus toxoid
- Temperature greater than or equal to 105°F within 48 hours of vaccination with no other identifiable cause
- Collapse or shock-like state within 48 hours of vaccination
- Persistent inconsolable crying lasting more than 3 hours within 48 hours of vaccination
- Convulsions with or without a fever within 3 days of vaccination
- PEDIARIX is available in vials and 2 types of prefilled syringes. One type of prefilled syringe has a tip cap which may contain natural rubber latex and a plunger which does not contain latex. The other type has a tip cap and a rubber plunger which contain dry natural latex rubber. Use of these syringes may cause allergic reactions in latex sensitive individuals.

FURTHER POINTS

- Continue to give a birth dose of single-antigen Hep B vaccine soon after birth and before hospital discharge. You may follow with 3 doses of Pediarix, spaced appropriately, to children without contraindications. This 4-dose Hep B series is considered acceptable as long as the last dose of Hep B vaccine is given at/after age 6 months.
- Pediarix does not contain a preservative. After removal of the dose, any remaining vaccine should be discarded.
- The combined DTaP-IPV-Hep B vaccine may be used when any component of the vaccine is indicated, and if the other components are not contraindicated.
- There is not a separate Vaccine Information Statement (VIS) for Pediarix. Use the current VISs for DTaP, IPV, and Hep B or the Multi-vaccine VIS available at <http://www.cdc.gov/vaccines/pubs/vis/default.htm>

For additional information, refer to VFC Program Resolutions on “Vaccines to Prevent Diphtheria, Tetanus and Pertussis,” “Vaccines to Prevent Poliomyelitis,” “Vaccines to Prevent Hepatitis B” and the ACIP Recommendations on the use of DTaP, IPV and HepB vaccines, located at <http://www.cdc.gov/vaccines/recs>