



Commonly Asked Questions on Pediarix and Pentacel

Pediarix Questions and Answers

What is the dosing schedule for the DTaP-IPV-HepB combination vaccine (Pediarix by GSK)?

Pediarix contains the vaccine components DTaP, IPV, and hepatitis B. The primary series is 3 doses (0.5 mL) given intramuscularly at 2, 4, and 6 months of age. It should not be given to infants younger than 6 weeks of age nor to children 7 years or older.

Can Pediarix be given to infants born to mothers who are HBsAg-positive?

Yes, although the package inserts states that Pediarix should only be given to infants born to mothers who are HBsAg-negative, the ACIP voted on February 26, 2003, to expand its recommendations for use to also include infants born to mothers whose HBsAg status is positive or unknown beginning no earlier than age 6 weeks.

Can Pediarix be used in infants and children who have fallen behind?

Yes. As with any combination vaccine, it may be used when any of the components are indicated and none are contraindicated. Providers must observe spacing intervals such that the minimum interval between doses is equal to the greatest interval of any of the individual antigens. The vaccine may only be used in children younger than age 7 years.

We have been routinely giving DTaP-HepB-IPV (Pediarix; GSK) to toddlers who were overdue for their third doses of DTaP, IPV, and HepB. Recently someone told me that Pediarix is only intended for use at 2, 4, and 6 months of age. Did we give the vaccine in error?

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Pentacel Questions and Answers

Please describe how the combination vaccine Pentacel should be used.

FDA licensed Pentacel on June 20, 2008. It is approved for use as a 4-dose series in infants and children at ages 2, 4, 6, and 15-18 months. It should not be used for any dose in the primary series for children age 5 years or older or as the booster dose for children ages 4-6 years. The DTaP-IPV component is supplied as a sterile liquid, which is used to reconstitute lyophilized (freeze-dried) ActHIB vaccine. The two components of the vaccine should be stored together in the carton to reduce vaccine administration errors. The DTaP-IPV component should never be administered alone.

Can we give Pentacel to a child who has previously received separate injections of one or more of these antigens?

Yes, as long as minimum intervals are maintained.

We inadvertently gave a child only the DTaP-IPV component of Pentacel (DTaP-IPV/Hib; sanofi pasteur), not realizing that this component was intended to reconstitute the Hib component. Does this count as a valid dose of DTaP and IPV? Can we mix the unused Hib component with sterile water and give it separately?

Use of DTaP-IPV solution as the diluent for the Hib component is specifically written both on the Pentacel box AND on the DTaP-IPV vial label. In answer to your first question, the DTaP-IPV component will count as valid doses of DTaP and IPV vaccines, but take measures to prevent this error in the future. In answer to your second question, NO, you cannot mix the Hib component with sterile water. ActHib must ONLY be reconstituted with either the DTaP-IPV solution

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No, the vaccine was not given in error. Pediarix is licensed for use in children ages 6 weeks through 6 years for doses 1, 2, and 3 of the DTaP primary series. This would not constitute a vaccine error, as long as you observe the recommended minimum intervals for all the vaccine components (i.e., DTaP, IPV, and HepB).

We have been giving DTaP-HepB-IPV (Pediarix) to children who are overdue for DTaP #4, IPV #3, and HepB #3. Is this an acceptable practice?

No. Pediarix is intended to be used only for doses 1, 2, or 3 of the DTaP primary series; consequently using Pediarix for DTaP #4 is off-label and not recommended. You should take measures to prevent this error in the future. The DTaP, IPV, and HepB doses given in this scenario do not need to be repeated as long as you met the recommended minimum intervals for each vaccine component (DTaP, IPV, HepB). If you did meet the minimum intervals, the doses should be counted as valid.

****IMPORTANT REMINDER****

If you have not yet completed the “You Call the Shots” online modules please click on the following link for instructions on how to complete these modules:

<http://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/providers/communications/2013/educational-requirement-letter-instructions.pdf>

Please contact Jodi Dore at 207-287-3746 for any further questions.

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supplied with Pentacel, or with a specific ActHib diluent. If you have ActHib but neither diluent, you must contact the manufacturer (sanofi pasteur) and obtain ActHib diluent.

Can we give Pentacel if we don't know the type of DTaP vaccine the child previously received?

Yes. CDC recommends that whenever feasible, only one manufacturer's DTaP product be used for the entire pertussis series, but that vaccinations should not be deferred if the DTaP product previously given is unavailable or unknown.

When we give the combination DTaP-IPV/Hib vaccine (Pentacel by sanofi) for the primary series to a child at ages 2, 4, 6, and 15–18 months, the child receives a total of 4 doses of IPV. Does the child still need a booster dose of IPV before entering kindergarten?

Yes. In summer 2009, ACIP updated its recommendations for use of inactivated poliovirus vaccines (IPV), partly in response to the availability of newer combination vaccines (e.g., Pentacel) that include an IPV component. ACIP now recommends that children receive at least 1 dose of IPV at age 4 through 6 years, even if they have previously received 4 doses. The interval between the next-to-last and last dose should be at least 6 months. (Note: This updated recommendation applies to all IPV-containing vaccines, including combination vaccines as well as IPV given as a single product.) This means that some children may receive a total of 5 doses, a practice ACIP considers acceptable. This is similar to the recommendation for the last dose in the DTaP series.

**If you have any questions, please contact the Maine Immunization Program at:
Phone (207) 287-3746 or (800) 867-4775**

