

Kinrix[®]
**Immunogenicity, Safety,
Indications, and Use**

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Outline

- **Overview of Kinrix[®]**
- **Safety data**
- **Immunogenicity**
- **Indications and Uses**
- **Notice to Readers**

Overview of Kinrix[®]

- **Composition**
 - ***Kinrix[®]* (DTaP-IPV)**
 - **GlaxoSmithKline Biologicals [GSK]**
 - ***Infanrix[®]* (DTaP)**
 - ***Pediarix[®]* (DTaP-HepB-IPV)**
- **Presentation**
 - **Single injectable vaccine**

Components of Kinrix[®] and other DTaP Vaccines

Vaccine Antigenic Component	DAPTACEL (DTaP)	Infanrix (DTaP)	Tripedia (DTaP)	TriHIBit (Tripedia + ActHIB)	Pediarix (Infanrix + IPV + HBV)	Kinrix (Infanrix + IPV)	Pentacel (DTaP + IPV + Hib)	Quadracel* (DTaP + IPV)
Manufacturer	sp	GSK	sp	sp	GSK	GSK	sp	sp
PT (µg)	10	25	23.4	23.4	25	25	20	20
FHA (µg)	5	25	23.4	23.4	25	25	20	20
PRN (µg)	3	8			8	8	3	3
FIM 2 + 3 (µg)	5						5	5
D (Lf)	15	25	6.7	6.7	25	25	15	15
T (Lf)	5	10	5	5	10	10	5	5
IPV T1 (Mahoney) (DAU)					40	40	40	40
Polio T2 (MEF-1) (DAU)					8	8	8	8
Polio T3 (Saukett) (DAU)					32	32	32	32
Hib (PRP-T) (ActHIB) (units/ug Tetanus toxoid conj)				10/24			10/24	
HbsAg recombinant protein (mcg)					10			

* Not approved for use in U.S.

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Safety Data

- **Two trial groups**
 - Injection of combined DTaP-IPV vaccine
 - Two separate injections, DTaP + IPV
- **Injected site pain**
 - The most common adverse event in both groups
 - Small statistically significant difference for “any” or “grade 3” pain in DTaP-IPV recipients
- **Large swellings with severe (Grade 3) functional impairment**
 - In DTaP-IPV recipients (N=3156) there were 7 cases (0.2%)
 - In DTaP + IPV recipients (N=1053) there was 1 case (0.1%)
- **No reports associated with other serious adverse events or deaths**

Immunogenicity

- **The immunologic responses following Kinrix[®] were similar to those following separately administered component vaccines**
- **When co-administered with measles, mumps, and rubella (MMR) vaccine, DTaP-IPV had no effect on immunogenicity**

Mix and Match Issues

“The ACIP has recommended that, whenever feasible, the same manufacturer’s DTaP product should be used for the primary series but that vaccination should not be deferred if the specific DTaP vaccine brand previously administered is unavailable or unknown.”

*(Combination Vaccines for Childhood Immunization
MMWR Vol 48/No RR-5, May 14, 1999)*

Indications and Uses

- **DTaP-IPV is administered as intramuscular injection into the deltoid region**
- **DTaP-IPV is indicated for use**
 - **as the fifth dose of DTaP**
 - **and fourth dose (booster doses) of IPV**
 - **in children aged 4-6 years who received DTaP and/or DTaP-HepB-IPV as the first three doses and DTaP as the fourth dose**

Proposed Notice to Readers

- To be published in the **Morbidity and Mortality Weekly Report (MMWR)**
- **[Notice to Readers:] FDA Licensure of Diphtheria and Tetanus Toxoids and Acellular Pertussis and Inactivated Poliovirus Vaccine (Kinrix®) for use as a Booster Dose in Children Aged 4 to 6 years**

Thank you !