**Diphtheria Tetanus Acellular Pertussis-Inactivated Poliovirus**

**(DTaP-IPV) Combination Vaccine (QUADRACEL®)**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunization.

**Indications and Usage**

**QUADRACEL®** is indicated for active immunization against diphtheria, tetanus, pertussis, and poliomyelitis. **QUADRACEL®** (DTaP-IPV) is approved for the fifth dose in the DTaP vaccine series and the fourth or fifth dose in the IPV series in children 4 through 6 years of age who have received four doses of DTaP-IPV-Hib (PENTACEL®) and/or DTaP (DAPTACEL®) vaccine.

**Recommended Schedule**

Give a single dose in children 4 through 6 years of age who meet eligibility requirements. The minimum interval from dose 4 to dose 5 should be at least 6 months to provide an optimum booster response. Note that the final dose in the IPV series must be administered at age ≥4 years regardless of the number of previous doses, and with a minimum interval of 6 months from the previous dose.

**Dosage**

**QUADRACEL®** is to be administered as a single 0.5 mL dose by intramuscular (IM) injection. **QUADRACEL®**is available in suspension for injection, supplied in single dose (0.5 mL) vials.

**Preparation for Administration**

**Shake the vial well, until a uniform, white, cloudy suspension results before use. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the product should not be administered.**

**Anatomical Site**

The preferred site of administration is the deltoid muscle of the upper arm.

**Do not administer QUADRACEL® intravenously, intradermally, or subcutaneously.**

**Precautions**

If Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including **QUADRACEL®**, should be based on careful consideration of the potential benefits and possible risks.

Carefully consider benefits and risks before administering **QUADRACEL®** to persons with a history of:

* Fever 40.5˚ C or higher (105˚ F or higher), hypotonic-hyporesponsive episode (HHE) or persistent, incolsolable crying lasting 3 hours or longer within 48 hours after a previous pertussis-containing vaccine.
* Seizures with/without fever within 3 days after a previous pertussis-containing vaccine.

**Contraindications**

Individuals with:

* Anaphylactic reaction to previous dose of any diphtheria toxoid, tetanus toxoid, pertussis, or poliovirus-containing vaccines, or to any component of **QUADRACEL®**.
* Encephalopathy within 7 days of administration of a previous dose of a pertussis containing vaccine with no other identifiable cause.
* Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy is a contraindication of any pertussis-containing vaccine.

**Adverse Events**

* See the product’s package insert.
* See Adverse Events Following Vaccinations page of this section.

**Storage and Handling**

* Store in refrigerator at 35˚F - 46˚F (2˚C - 8˚C).
* DO NOT FREEZE; discard if product has been frozen.
* Do not use after expiration date on label.

**Additional Information**

* **“Indications and Guidance for Use:** DTaP-IPV(**QUADRACEL®**) is indicated for use as the fifth dose of DTaP and fourth or fifth dose of IPV in children aged 4 through 6 years who received four doses of PENTACEL® and/or DAPTACEL® vaccine. This vaccine should not be administered to children aged less than 4 years of aged 7 years and older; however, if DTaP-IPV (**QUADRACEL®**) is inadvertently administered for an earlier dose of the DTap and/or IPV series, the dose should be counted as valid and does not need to be repeated provided minimum interval requirements have been met (*5*). Note that the final dose in the IPV series must be administered at age ≥4 years regardless of the number of previous doses, and with a minimum interval of 6 months from the previous dose. **Data are limited on the safety and immunogenicity of interchanging DTaP vaccines from different manufacturers (***6*). **ACIP recommends that, whenever feasible, the same manufacturer’s DTap vaccines should be used for each dose in the series; however, vaccination should not be deferred because the type of DTaP previously administered is unavailable or unknown.”** (*MMWR Morb Mortal Wkly Rep.* 2015 Sep 4;64(34):948-9).
* Vaccine Information Statements – There is no specific Vaccine Information Statement (VIS) for **QUADRACEL®**. When administering a combination vaccine, the VIS for the individual component vaccines must be supplied.
* ACIP has clarified the poliovirus vaccination schedule to be used for specific combination vaccines. When DTap-IPV/Hib (PENTACEL®) is used to provide 4 doses at ages 2, 4, 6, and 15 through 18 months, an additional booster dose of age-appropriate IPV-containing vaccine (IPV [IPOL] or DRaP-IPV (KINRIX® [or **QUADRACEL®**]) should be administered at age 4 through 6 years. This will result in a 5-dose IPV vaccine series, which is considered acceptable by ACIP. DTaP-IPV/Hib (PENTACEL®) is not indicated for the booster dose at age 4 through 6 years. ACIP recommends that the minimum interval from dose 4 to dose 5 should be at least 6 months to provide an optimum booster response. In accordance with existing recommendations, if a child misses an IPV dose at age 4 through 6 years, the child should receive a booster dose as soon as feasible (*MMWR Morb Mortal Wkly Rep* August 7, 2009/58(30); 830).

**References**

Liang J, Wallace G, Mootrey G. Licensure of a Diphtheria and Tetanus Toxoids and Acellular Pertussis Absorbed and Inactivated Poliovirus Vaccine and Guidance for Use as a Booster Dose. *MMWR Morb Mortal Wkly Rep.* 2015 Sep 4;64(34):948-9.

**QUADRACEL®** Package Insert (dated 03/2015)

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM439903.pdf>

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