

Approval Date: [December 19, 2019](#)

Product: Quadracel

Proper Name: Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine

Manufacturer: Sanofi Pasteur Limited

Indication: Active immunization against diphtheria, tetanus, pertussis and poliomyelitis.

Description: Quadracel (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine) is a sterile suspension for intramuscular injection.

BLA: BL 125525

Regulatory Milestone:

On March 24, 2014, Sanofi Pasteur Limited (license #1726), submitted a Biologics License Application (BLA) for Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine [DTaP-IPV], with the proposed trade name, Quadracel. The manufacturing information for Quadracel is incorporated by cross-reference from the Applicant's approved Pentacel vaccine file submitted under STN 125145 (Originally submitted July 26, 2005).

PDUFA Goal Date: March 24, 2015

Package Insert: [Package Insert - Quadracel](#)

Summary Basis for Regulatory Approval: [March 24, 2015 Summary Basis for Regulatory Action – Quadracel](#)

European Public Assessment Report: No data

Advisory Committee:

No issues requiring the input of an Advisory Committee were identified.

Safety:

The safety data from studies M5I02 and Td508 are adequate to support licensure of Quadracel.

NCT Numbers:

- NCT00255047

EudraCT Numbers:

- 2015-005589-43

Publications:

- Mosley, J. F., 2nd, Smith, L. L., Parke, C. K., Brown, J. A., LaFrance, J. M., & Clark, P. K. (2016). Quadracel: Vaccination Against Diphtheria, Tetanus, Pertussis, and Poliomyelitis in Children. *P & T: a peer-reviewed journal for formulary management*, 41(4), 238–253.
- Liang, J., Wallace, G., & Mootrey, G. (2015). Licensure of a Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine and Guidance for Use as a Booster Dose. *MMWR. Morbidity and mortality weekly report*, 64(34), 948–949.
<https://doi.org/10.15585/mmwr.mm6434a5>
- Halperin, S. A., Tapiero, B., Law, B., Diaz-Mitoma, F., Duval, B., Langley, J. M., Elrick, D. B., & Jacquet, J. M. (2006). Interchangeability of two diphtheria and tetanus toxoids, acellular pertussis, inactivated poliovirus, Haemophilus influenzae type b conjugate vaccines as a fourth dose in 15-20-month-old toddlers. *Vaccine*, 24(18), 4017–4023.
<https://doi.org/10.1016/j.vaccine.2005.11.012>