

Approval Date: [November 6, 2019](#)

Product: INFANRIX

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

Manufacturer: GlaxoSmithKline Biologicals

Indication: For active immunization against diphtheria, tetanus, and pertussis as a 5-dose series in infants and children aged 6 weeks through 6 years (prior to the 7th birthday).

Description: INFANRIX (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) is a noninfectious, sterile vaccine for intramuscular administration. Each 0.5-mL dose is formulated to contain 25 Lf of diphtheria toxoid, 10 Lf of tetanus toxoid, 25 mcg of inactivated pertussis toxin (PT), 25 mcg of filamentous hemagglutinin (FHA), and 8 mcg of pertactin (69 kiloDalton outer membrane protein).

BLA: BL 103647

Regulatory Milestone: No data available

PDUFA Goal Date: No data available

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

Summary Basis for Regulatory Approval: [Summary Basis for Regulatory Action - Infanrix](#)

European Public Assessment Report:

- [Human medicine European public assessment report \(EPAR\): Infanrix HepB](#)

- [Human medicine European public assessment report \(EPAR\): Infanrix Penta](#)
- [Human medicine European public assessment report \(EPAR\): Infanrix Hexa](#)

Advisory Committee:

Data regarding the safety and efficacy of Infanrix were presented and discussed at "the July 10, 1996 meeting of the FDA's Vaccines and Related Biological Products Advisory Committee meeting.

NCT Numbers:

- NCT01353703
- NCT01309646
- NCT00835237
- NCT01086423
- NCT01577732
- NCT00696423
- NCT01449812
- NCT01094171
- NCT00753649
- NCT00871741
- NCT01457547
- NCT01453998
- NCT01248884
- NCT01090453
- NCT01171989
- NCT00369824
- NCT01110044
- NCT00970307
- NCT01323647
- NCT00169481
- NCT01267058
- NCT01235949
- NCT02096263
- NCT01738477
- NCT00452686
- NCT02052596
- NCT02377349
- NCT01988857
- NCT01755689
- NCT01767376
- NCT03311659
- NCT00426361
- NCT02753413
- NCT00609492
- NCT02173704
- NCT01929291
- NCT02798952
- NCT00390910
- NCT00964028
- NCT01616459
- NCT00297856
- NCT01262924
- NCT01568060
- NCT00345358
- NCT00135486
- NCT00406562
- NCT00544271
- NCT00376779
- NCT02858440
- NCT00489970
- NCT01153841
- NCT01245049
- NCT00338351
- NCT00627458
- NCT01171963
- NCT02422264
- NCT00614614
- NCT00635128
- NCT00908115
- NCT00412854
- NCT01457495
- NCT01627561
- NCT00345579
- NCT00322335
- NCT02853929
- NCT00263692
- NCT00148941
- NCT02360475
- NCT03128489
- NCT01147900
- NCT00327184
- NCT00610168
- NCT03188458
- NCT00586612
- NCT00197236
- NCT00289796
- NCT00508261
- NCT02052661
- NCT00290342
- NCT00548171
- NCT00871000
- NCT01362322
- NCT00307034
- NCT00611559
- NCT01119625
- NCT01204658
- NCT00370396
- NCT01144663
- NCT00466947
- NCT01003418
- NCT00454987
- NCT00282295
- NCT00385255
- NCT00258700
- NCT01277705
- NCT00370318
- NCT00346073
- NCT01340898
- NCT01457560
- NCT01457508

- NCT01153893
- NCT00513409
- NCT01323959
- NCT00325143
- NCT00146835
- NCT00370227
- NCT02072525
- NCT00879827
- NCT00289783
- NCT00127855
- NCT04535037
- NCT01345240
- NCT02447978
- NCT04138056
- NCT00129116

EudraCT Numbers:

- 2004-001823-39
- 2012-002426-70
- 2015-001530-25
- 2012-002401-22
- 2015-001513-27
- 2006-006680-23
- 2012-002439-26
- 2005-003052-36
- 2007-001167-29
- 2013-002538-18
- 2009-016911-39
- 2015-001510-10
- 2006-001934-42
- 2013-002804-15
- 2012-003324-20
- 2013-004304-19
- 2013-003428-34
- 2005-005421-59
- 2006-005733-38
- 2006-000556-41
- 2012-004137-16
- 2005-003437-41
- 2006-000559-16
- 2004-001223-37
- 2005-003300-11
- 2012-004513-14
- 2014-001120-30
- 2007-000596-42
- 2015-001507-31
- 2011-005868-25
- 2013-002821-41
- 2007-004002-26
- 2006-000549-20
- 2006-000560-93
- 2004-003769-33
- 2015-003391-74
- 2007-000304-32
- 2006-001482-42
- 2010-019253-18
- 2006-000558-30
- 2005-003299-40
- 2006-004129-27
- 2015-001512-35
- 2006-000553-22
- 2015-001508-71
- 2008-006365-91
- 2006-006460-32
- 2012-002427-15
- 2006-001481-17
- 2015-001449-93
- 2013-003427-10
- 2006-003239-61
- 2005-004770-24
- 2010-022538-10
- 2004-001249-14
- 2008-007846-69
- 2004-000397-31
- 2007-005343-16
- 2006-001628-38
- 2011-002076-16
- 2006-000554-46
- 2012-005200-18
- 2015-001511-12
- 2011-005604-15
- 2014-001117-41
- 2006-003762-33
- 2011-001508-37
- 2013-005577-43
- 2011-002946-11
- 2006-000898-30
- 2012-002428-34
- 2009-012202-39
- 2006-000518-19
- 2013-002537-37
- 2011-000876-33
- 2009-016841-24
- 2012-000162-38
- 2016-000274-37
- 2012-003026-25
- 2005-001288-73
- 2011-000943-26
- 2008-006551-51
- 2010-021491-28
- 2014-000101-12
- 2010-019730-27
- 2006-002898-47
- 2013-004194-27
- 2005-002352-18
- 2011-004638-32
- 2005-006066-34
- 2004-001175-19
- 2012-000819-82
- 2010-021569-58
- 2013-003488-71
- 2012-000826-23
- 2014-001119-38
- 2010-022303-22
- 2010-021490-37
- 2008-001457-18

- 2007-007781-38
- 2009-016635-36
- 2009-012460-14
- 2008-001592-30

Publications:

- Denoël, P. A., Goldblatt, D., de Vleeschauwer, I., Jacquet, J. M., Pichichero, M. E., & Poolman, J. T. (2007). Quality of the Haemophilus influenzae type b (Hib) antibody response induced by diphtheria-tetanus-acellular pertussis/Hib combination vaccines. *Clinical and vaccine immunology: CVI*, 14(10), 1362–1369. <https://doi.org/10.1128/CVI.00154-07>
- Hodgson, A., Forgor, A. A., Chandramohan, D., Reed, Z., Binka, F., Bevilacqua, C., Boutriau, D., & Greenwood, B. (2008). A phase II, randomized study on an investigational DTPw-HBV/Hib-MenAC conjugate vaccine administered to infants in Northern Ghana. *PLoS one*, 3(5), e2159. <https://doi.org/10.1371/journal.pone.0002159>
- Martins, R., Camacho, L. A., Marcovistz, R., Noronha, T. G., Maia, M., dos Santos, E. M., Barbosa, G. G., Silva, A. M., Souza, P. C., Lemos, M. C., & Homma, A. (2008). Immunogenicity, reactogenicity and consistency of production of a Brazilian combined vaccine against diphtheria, tetanus, pertussis and Haemophilus influenzae type b. *Memorias do Instituto Oswaldo Cruz*, 103(7), 711–718. <https://doi.org/10.1590/s0074-02762008000700014>
- Espinoza, F., Tregnaghi, M., Gentile, A., Abarca, K., Casellas, J., Collard, A., Lefevre, I., & Jacquet, J. M. (2010). Primary and booster vaccination in Latin American children with a DTPw-HBV/Hib combination: a randomized controlled trial. *BMC infectious diseases*, 10, 297. <https://doi.org/10.1186/1471-2334-10-297>
- Quiambao, B., Van Der Meeren, O., Kolhe, D., & Gatchalian, S. (2012). A randomized, dose-ranging assessment of the immunogenicity and safety of a booster dose of a combined diphtheria-tetanus-whole cell pertussis-hepatitis B-inactivated poliovirus-Hemophilus influenzae type b (DTPw-HBV-IPV/Hib) vaccine vs. co-administration of DTPw-HBV/Hib and IPV vaccines in 12 to 24 months old Filipino toddlers. *Human vaccines & immunotherapeutics*, 8(3), 347–354. <https://doi.org/10.4161/hv.18630>
- Dbaibo, G., El-Ayoubi, N., Ghanem, S., Hajar, F., Bianco, V., Miller, J. M., & Mesaros, N. (2013). Immunogenicity and safety of a quadrivalent meningococcal serogroups A, C, W-135 and Y tetanus toxoid conjugate vaccine (MenACWY-TT) administered to adults aged 56

- Years and older: results of an open-label, randomized, controlled trial. *Drugs & aging*, 30(5), 309–319. <https://doi.org/10.1007/s40266-013-0065-0>
- Hammitt, L. L., Ojal, J., Bashraheil, M., Morpeth, S. C., Karani, A., Habib, A., Borys, D., Goldblatt, D., & Scott, J. A. (2014). Immunogenicity, impact on carriage and reactogenicity of 10-valent pneumococcal non-typeable Haemophilus influenzae protein D conjugate vaccine in Kenyan children aged 1-4 years: a randomized controlled trial. *PloS one*, 9(1), e85459. <https://doi.org/10.1371/journal.pone.0085459>
 - Munoz, F. M., Bond, N. H., Maccato, M., Pinell, P., Hammill, H. A., Swamy, G. K., Walter, E. B., Jackson, L. A., Englund, J. A., Edwards, M. S., Healy, C. M., Petrie, C. R., Ferreira, J., Goll, J. B., & Baker, C. J. (2014). Safety and immunogenicity of tetanus diphtheria and acellular pertussis (Tdap) immunization during pregnancy in mothers and infants: a randomized clinical trial. *JAMA*, 311(17), 1760–1769. <https://doi.org/10.1001/jama.2014.3633>
 - Leonardi, M., Latiolais, T., Sarpong, K., Simon, M., Twiggs, J., Lei, P., Rinderknecht, S., Blatter, M., Bianco, V., Baine, Y., Friedland, L. R., & Miller, J. M. (2015). Quadrivalent meningococcal (MenACWY-TT) conjugate vaccine or a fourth dose of H. influenzae-N. meningitidis C/Y conjugate vaccine (HibMenCY-TT) is immunogenic in toddlers who previously received three doses of HibMenCY-TT in infancy. *Vaccine*, 33(7), 933–941. <https://doi.org/10.1016/j.vaccine.2014.08.027>
 - Leonardi, M., Latiolais, T., Sarpong, K., Simon, M., Twiggs, J., Lei, P., Rinderknecht, S., Blatter, M., Bianco, V., Baine, Y., Friedland, L. R., Baccarini, C., & Miller, J. M. (2015). Immunogenicity and reactogenicity of Infanrix™ when co-administered with meningococcal MenACWY-TT conjugate vaccine in toddlers primed with MenHibrix™ and Pediarix™. *Vaccine*, 33(7), 924–932. <https://doi.org/10.1016/j.vaccine.2014.09.064>
 - Dalvi, S., Kulkarni, P. S., Phadke, M. A., More, S. S., Lalwani, S. K., Jain, D., Manglani, M., Garg, B. S., Doibale, M. K., Deshmukh, C. T., & SIIL DTwP + HepB Hib Author Group (2015). A comparative clinical study to assess safety and reactogenicity of a DTwP-HepB+Hib vaccine. *Human vaccines & immunotherapeutics*, 11(4), 901–907. <https://doi.org/10.1080/21645515.2015.1010953>
 - Vandermeulen, C., Theeten, H., Rathi, N., Kuriyakose, S., Han, H. H., Sokal, E., Hoppenbrouwers, K., & Van Damme, P. (2015). Decennial administration in young adults of

a reduced-antigen content diphtheria, tetanus, acellular pertussis vaccine containing two different concentrations of aluminium. *Vaccine*, 33(26), 3026–3034.

<https://doi.org/10.1016/j.vaccine.2014.10.049>

- Vandermeulen, C., Theeten, H., Rathi, N., Kuriyakose, S., Han, H. H., Sokal, E., Hoppenbrouwers, K., & Van Damme, P. (2015). Decennial administration in young adults of a reduced-antigen content diphtheria, tetanus, acellular pertussis vaccine containing two different concentrations of aluminium. *Vaccine*, 33(26), 3026–3034.
<https://doi.org/10.1016/j.vaccine.2014.10.049>
- Kovac, M., Rathi, N., Kuriyakose, S., Hardt, K., & Schwarz, T. F. (2015). Immunogenicity and reactogenicity of a decennial booster dose of a combined reduced-antigen-content diphtheria-tetanus-acellular pertussis and inactivated poliovirus booster vaccine (dTpa-IPV) in healthy adults. *Vaccine*, 33(22), 2594–2601. <https://doi.org/10.1016/j.vaccine.2015.03.104>
- Bona, G., Castiglia, P., Zoppi, G., de Martino, M., Tasciotti, A., D'Agostino, D., Han, L., & Smolenov, I. (2016). Safety and immunogenicity of a CRM or TT conjugated meningococcal vaccine in healthy toddlers. *Vaccine*, 34(29), 3363–3370.
<https://doi.org/10.1016/j.vaccine.2016.05.009>
- Borja-Tabora, C., Peyrani, P., Webber, C., Van der Wielen, M., Chevart, B., De Schrevel, N., Bianco, V., Aris, E., Cutler, M., Li, P., & Perez, J. L. (2020). A phase 2b/3b MenACWY-TT study of long-term antibody persistence after primary vaccination and immunogenicity and safety of a booster dose in individuals aged 11 through 55 years. *BMC infectious diseases*, 20(1), 426. <https://doi.org/10.1186/s12879-020-05104-5>