

Approval Date: [July 2, 2020](#)

Product: Fluarix Quadrivalent

Proper Name: Influenza Vaccine

Manufacturer: GlaxoSmithKline's Biologicals

Indication: FLUARIX QUADRIVALENT is a vaccine indicated for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FLUARIX QUADRIVALENT is approved for use in persons aged 6 months and older.

Description: FLUARIX QUADRIVALENT, Influenza Vaccine, for intramuscular injection, is a sterile, colorless, and slightly opalescent suspension. FLUARIX QUADRIVALENT is prepared from influenza viruses propagated in embryonated chicken eggs.

BLA: BL 125127

Regulatory Milestone:

Fluarix was licensed in the U.S. on August 31, 2005, for the prevention of influenza subtypes A and type B contained in the vaccine under the accelerated approval regulations. The efficacy of Fluarix was confirmed in this clinical endpoint study and Fluarix was granted 'traditional approval' on October 2, 2009. Expansion of the age indication for children aged 3 years and older was approved on October 19, 2009 (STN 125127/319). Fluarix Quadrivalent (D-QIV) formulation was approved on December 14, 2012, under STN 125127/513 for use in persons 3 years of age and older. Submitted the clinical study report to the IND on January 18, 2017, to fulfill the post-marketing study commitment.

PDUFA Goal Date: January 12, 2018

Package Insert: [Package Insert - Fluarix Quadrivalent](#)

Summary Basis for Regulatory Approval: [January 11, 2018 SBRA Fluarix Quadrivalent](#)

European Public Assessment Report: None

Advisory Committee:

This submission was not discussed at a VRBPAC meeting because review of this submission did not identify concerns or issues which would have benefited from an advisory committee discussion.

NCT Numbers:

- NCT02148211
- NCT03701061
- NCT03686514
- NCT01959945
- NCT03694392
- NCT03275389
- NCT02545543
- NCT03722589
- NCT02207413
- NCT03615482
- NCT01954251
- NCT02222870
- NCT02539108
- NCT01946425
- NCT02908269
- NCT03438487
- NCT04109222
- NCT03965195
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- NCT04551677
- NCT04460781
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- NCT03698279
- NCT03328325
- NCT03617523
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- NCT03736759
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- NCT04074928
- NCT02876159
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- NCT01198756
- NCT01196975
- NCT00952705
- NCT01997450
- NCT01992107
- NCT03658629
- NCT01992094
- NCT03312699
- NCT03318315
- NCT03068949
- NCT02860039
- NCT03734237

EudraCT Numbers:

- 2013-003155-38
- 2012-002587-27
- 2018-001894-26
- 2016-004133-25
- 2018-005026-39
- 2013-001094-25
- 2010-021034-63
- 2019-004721-24
- 2010-021032-34
- 2010-020312-12
- 2016-001557-41
- 2014-004634-26
- 2014-001118-24
- 2011-000758-41
- 2014-000955-10
- 2013-000372-15

Publications:

- Zerbini, C. A., Ribeiro Dos Santos, R., Jose Nunes, M., Soni, J., Li, P., Jain, V. K., & Ofori-Anyinam, O. (2017). Immunogenicity and safety of Southern Hemisphere inactivated quadrivalent influenza vaccine: a Phase III, open-label study of adults in Brazil. *The Brazilian journal of infectious diseases : an official publication of the Brazilian Society of Infectious Diseases*, 21(1), 63–70. <https://doi.org/10.1016/j.bjid.2016.10.003>

- Graaf, H. d., & Faust, S. N. (2015). Fluarix quadrivalent vaccine for influenza. *Expert review of vaccines*, 14(8), 1055–1063. <https://doi.org/10.1586/14760584.2015.1057573>
- McKeage K. (2013). Inactivated quadrivalent split-virus seasonal influenza vaccine (Fluarix® quadrivalent): a review of its use in the prevention of disease caused by influenza A and B. *Drugs*, 73(14), 1587–1594. <https://doi.org/10.1007/s40265-013-0114-3>
- Grohskopf, L. A., Sokolow, L. Z., Broder, K. R., Walter, E. B., Fry, A. M., & Jernigan, D. B. (2018). Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices-United States, 2018-19 Influenza Season. *MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports*, 67(3), 1–20. <https://doi.org/10.15585/mmwr.rr6703a1>
- Dos Santos, G., Shende, V., Damaso, S., & Yeakey, A. (2019). Enhanced Safety Surveillance of GSK's Quadrivalent Seasonal Influenza Vaccine in Belgium, Germany, and Spain for the 2018/19 Season: Interim Analysis. *Advances in therapy*, 36(12), 3340–3355. <https://doi.org/10.1007/s12325-019-01105-2>
- Clements, K. M., Meier, G., McGarry, L. J., Pruttivarasin, N., & Misurski, D. A. (2014). Cost-effectiveness analysis of universal influenza vaccination with quadrivalent inactivated vaccine in the United States. *Human vaccines & immunotherapeutics*, 10(5), 1171–1180. <https://doi.org/10.4161/hv.28221>
- de Lusignan, S., Dos Santos, G., Byford, R., Schuind, A., Damaso, S., Shende, V., McGee, C., Yonova, I., & Ferreira, F. (2018). Enhanced Safety Surveillance of Seasonal Quadrivalent Influenza Vaccines in English Primary Care: Interim Analysis. *Advances in therapy*, 35(8), 1199–1214. <https://doi.org/10.1007/s12325-018-0747-4>