

Approval Date: [August 31, 2016](#)

Product: FLUCELVAX™

Proper Name: Influenza Vaccine

Manufacturer: Seqirus, Inc.

Indication: For active immunization of persons 4 years of age and older for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

Description: FLUCELVAX (Influenza Vaccine), a vaccine for intramuscular injection, is a subunit influenza vaccine prepared from virus propagated in Madin Darby Canine Kidney (MDCK) cells, a continuous cell line.

BLA: 125408

Regulatory Milestone:

PDUFA Goal Date: July 22, 2016

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

Summary Basis for Regulatory Approval: [May 23, 2016 Summary Basis of Regulatory Action - Flucelvax](#)

European Public Assessment Report: [Human medicine European public assessment report \(EPAR\): Flucelvax Tetra](#)

Advisory Committee:

The review committee determined that presentation of the supplement to the VRBPAC was not required because the data submitted to the supplement did not raise concerns or controversial issues which would have benefited from an advisory committee discussion.

Safety:

No safety signals were identified in the pre-licensure data. The applicant's plan to establish routine pharmacovigilance was found to be acceptable.

NCT Numbers:

- NCT03701061
- NCT00812110
- NCT01654224
- NCT00835926
- NCT03163342
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EudraCT Numbers:

- 2012-001223-13
- 2018-001857-29
- 2020-002785-13
- 2013-002081-39

Publications:

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- Lamb Y. N. (2019). Cell-Based Quadrivalent Inactivated Influenza Virus Vaccine (Flucelvax[®] Tetra/Flucelvax Quadrivalent[®]): A Review in the Prevention of Influenza. *Drugs*, *79*(12), 1337–1348. <https://doi.org/10.1007/s40265-019-01176-z>
- Bühler, S., & Ramharter, M. (2019). Flucelvax Tetra: a surface antigen, inactivated, influenza vaccine prepared in cell cultures. *ESMO open*, *4*(1), e000481. <https://doi.org/10.1136/esmoopen-2018-000481>
- Henry, C., Palm, A. E., Utset, H. A., Huang, M., Ho, I. Y., Zheng, N. Y., Fitzgerald, T., Neu, K. E., Chen, Y. Q., Krammer, F., Treanor, J. J., Sant, A. J., Topham, D. J., & Wilson, P. C. (2019). Monoclonal Antibody Responses after Recombinant Hemagglutinin Vaccine versus Subunit Inactivated Influenza Virus Vaccine: a Comparative Study. *Journal of virology*, *93*(21), e01150-19. <https://doi.org/10.1128/JVI.01150-19>

- Lamb Y. N. (2019). Correction to: Cell-Based Quadrivalent Inactivated Influenza Virus Vaccine (Flucelvax[®] Tetra/Flucelvax Quadrivalent[®]): A Review in the Prevention of Influenza. *Drugs*, 79(18), 2009. <https://doi.org/10.1007/s40265-019-01237-3>
- Moro, P. L., Winiecki, S., Lewis, P., Shimabukuro, T. T., & Cano, M. (2015). Surveillance of adverse events after the first trivalent inactivated influenza vaccine produced in mammalian cell culture (Flucelvax(®)) reported to the Vaccine Adverse Event Reporting System (VAERS), United States, 2013-2015. *Vaccine*, 33(48), 6684–6688. <https://doi.org/10.1016/j.vaccine.2015.10.084>
- Influenza Vaccines. (2020). In *Drugs and Lactation Database (LactMed)*. National Library of Medicine (US).
- Richards, K. A., Moritzky, S., Shannon, I., Fitzgerald, T., Yang, H., Branche, A., Topham, D. J., Treanor, J. J., Nayak, J., & Sant, A. J. (2020). Recombinant HA-based vaccine outperforms split and subunit vaccines in elicitation of influenza-specific CD4 T cells and CD4 T cell-dependent antibody responses in humans. *NPJ vaccines*, 5, 77. <https://doi.org/10.1038/s41541-020-00227-x>