

**Approval Date:** [January 28, 2020](#)

**Product:** Agriflu®

**Proper Name:** Influenza Virus Vaccine

**Manufacturer:** Seqirus Inc.

**Indication:** For active immunization of adults 18 years of age and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine.

**Description:** AGRIFLU, Influenza Virus Vaccine, for intramuscular injection is a trivalent inactivated influenza virus vaccine prepared from virus propagated in the allantoic cavity of embryonated hens' eggs inoculated with an influenza virus suspension containing kanamycin and neomycin sulphate.

**BLA:** 125297

**Regulatory Milestone:**

Agriflu received regulatory approval initially in Italy in 1986 as Agrippal, and is now approved for use in more than 50 countries worldwide. The initial formulation of Agrippal contained thimerosal as a preservative. The formulation was changed resulting in a trace-thimerosal vaccine that was marketed outside the U.S. starting in 2001. The applicant subsequently began producing a thimerosal-free formulation in 2003. Agriflu was approved for active immunization against influenza in adults 18 years of age and older on November 27, 2009.

**PDUFA Goal Date:** October 30, 2010

**Package Insert:** [Package Insert - Agriflu](#)

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

**European Public Assessment Report:** None

**Advisory Committee:**

This sBLA did not meet any of the factors for presentation to an advisory committee as described in FDA Draft Guidance, “Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings.” Therefore, the application was not discussed at a meeting of the Vaccines Related Products Advisory Committee.

**NCT Numbers:**

- NCT03701061
- NCT00812110
- NCT01654224
- NCT00835926
- NCT03163342
- NCT00561002
- NCT00831987
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- NCT02446912
- NCT01173601

**EudraCT Numbers:**

- 2014-005053-40
- 2014-004498-17
- 2012-003740-74

**Publications:**

- Sehatzadeh S. (2012). Influenza and pneumococcal vaccinations for patients with chronic obstructive pulmonary disease (COPD): an evidence-based review. *Ontario health technology assessment series*, 12(3), 1–64.
- Vajo Z. (2011). The seasonal influenza vaccine Agriflu(®). *Expert review of vaccines*, 10(11), 1513–1517. <https://doi.org/10.1586/erv.11.133>

- Munoz, F. M., Patel, S. M., Jackson, L. A., Swamy, G. K., Edwards, K. M., Frey, S. E., Petrie, C. R., Sendra, E. A., & Keitel, W. A. (2020). Safety and immunogenicity of three seasonal inactivated influenza vaccines among pregnant women and antibody persistence in their infants. *Vaccine*, 38(33), 5355–5363. <https://doi.org/10.1016/j.vaccine.2020.05.059>
- Influenza vaccine for 2020-2021. (2020). *The Medical letter on drugs and therapeutics*, 62(1607), 145–150.