

Approval Date: [July 2, 2019](#)

Product: Fluzone, Fluzone High-Dose and Fluzone Intradermal

Proper Name: Influenza Virus Vaccine

Manufacturer: Sanofi Pasteur, Inc (for Fluzone High-Dose and Fluzone Intradermal only)

Indication:

- Fluzone is indicated for active immunization of persons 6 months of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.
- Fluzone High-Dose is indicated for active immunization of persons 65 years of age and older against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.
- Fluzone Intradermal indicated for active immunization for use in adults 18 through 64 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

Description: Fluzone (Influenza Vaccine) for intramuscular injection is an inactivated influenza vaccine, prepared from influenza viruses propagated in embryonated chicken eggs.

BLA: BL 103914

Regulatory Milestone: No data

PDUFA Goal Date: April 30, 2015

Package Insert:

- [Package Insert - Fluzone](#)
- [Package Insert - Fluzone High-Dose](#)
- [Package Insert - Fluzone Intradermal](#)

Summary Basis for Regulatory Approval: [April 30, 2015 Summary Basis for Regulatory Action - Fluzone](#)

European Public Assessment Report: None

Advisory Committee:

This submission was not discussed at a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting because review of this submission did not identify concerns which would have benefitted from an advisory committee discussion.

NCT Numbers:

- NCT00831987
- NCT00835926
- NCT00561002
- NCT00831675
- NCT01685372
- NCT00836953
- NCT01205581
- NCT00258817
- NCT00812110
- NCT00389532
- NCT00389857
- NCT00258830
- NCT03701061
- NCT00743275
- NCT02133781
- NCT00755274
- NCT01654224
- NCT03163342
- NCT02141581
- NCT02222870
- NCT01978262
- NCT00524940
- NCT01827462
- NCT01938170
- NCT02539108
- NCT01232868
- NCT01262846
- NCT04109222
- NCT01189123
- NCT02908269
- NCT01946425
- NCT01987349
- NCT01691326
- NCT02250274
- NCT02154061
- NCT01720277
- NCT03028974
- NCT00623181
- NCT01666782
- NCT00436046
- NCT03158038
- NCT03614975
- NCT00570037
- NCT02134184
- NCT01215734
- NCT01933048
- NCT02649192
- NCT02461758
- NCT01146912
- NCT01644149
- NCT02566265
- NCT01522248
- NCT00844051
- NCT02876159
- NCT01227421
- NCT01436370
- NCT02474901
- NCT01662583
- NCT00138294
- NCT02438423
- NCT03564444
- NCT02266277
- NCT01959945
- NCT01910519
- NCT02872311
- NCT00693706
- NCT01246999
- NCT03186781
- NCT00555893
- NCT00283283
- NCT01009645
- NCT01664793
- NCT01831934
- NCT01646138
- NCT01216332
- NCT02609399

- NCT01416571
- NCT01971255
- NCT02371668
- NCT00439335
- NCT01733056
- NCT01055184
- NCT00741039
- NCT03870997
- NCT02056340
- NCT02743117
- NCT02473510
- NCT00867139
- NCT01023711
- NCT03308825
- NCT01111162
- NCT03617523
- NCT01579916
- NCT01859143
- NCT01974050
- NCT00902278
- NCT01788228
- NCT00921947
- NCT01688921
- NCT01023776
- NCT01059617
- NCT00677820
- NCT00943631
- NCT03058692
- NCT00402649
- NCT00873912
- NCT00966238
- NCT00819013
- NCT01578317
- NCT02563093
- NCT02258334
- NCT01946438
- NCT01691339
- NCT01104493
- NCT00988143
- NCT00538512
- NCT02783170
- NCT02165722
- NCT01868334
- NCT00264576
- NCT00943488
- NCT01147068
- NCT03239665
- NCT03318315
- NCT02967393
- NCT00390884
- NCT01258595
- NCT01737710
- NCT01173211
- NCT00539864
- NCT00112112
- NCT00943878
- NCT00765076
- NCT00963430
- NCT03283319
- NCT02807623
- NCT01264601
- NCT03312231
- NCT00703053
- NCT01430819
- NCT00885105
- NCT01612000
- NCT02290691
- NCT03232567
- NCT01248715
- NCT01181323
- NCT00992433
- NCT02915302
- NCT00992719
- NCT01427309
- NCT01011049
- NCT00388583
- NCT00772109
- NCT02242643
- NCT01974895
- NCT01712984
- NCT02212106
- NCT00858468
- NCT00905125
- NCT02285998
- NCT03165981
- NCT00551031
- NCT00391053
- NCT03143101
- NCT00383123
- NCT00391391
- NCT01218646
- NCT00845429
- NCT02572817
- NCT01240746
- NCT03282240
- NCT00775450
- NCT00753272
- NCT00764790
- NCT01196975
- NCT01198756
- NCT02545543
- NCT00377611
- NCT00630331
- NCT00461981
- NCT00980005
- NCT01196988
- NCT01162122
- NCT03497845
- NCT00944073
- NCT00529516
- NCT01928472
- NCT00992836
- NCT00963157
- NCT00772889
- NCT01204671
- NCT01793883
- NCT02914275
- NCT01068912
- NCT02035696
- NCT02680002
- NCT02214225
- NCT00735475
- NCT01052480
- NCT00645411
- NCT01855945
- NCT00771615
- NCT00985673
- NCT01776554
- NCT01766921
- NCT00385255
- NCT02603952
- NCT01992094
- NCT03315104
- NCT00943202
- NCT00959049
- NCT00412737
- NCT01857206
- NCT01992107
- NCT03698279
- NCT01776541
- NCT00992017
- NCT01314911
- NCT00344305
- NCT00510874
- NCT00945893
- NCT01231620
- NCT00860067
- NCT00453999
- NCT01227967
- NCT00705406
- NCT02532283
- NCT01091246
- NCT02207413
- NCT03314662
- NCT00391768
- NCT00958243
- NCT02256488
- NCT00521586
- NCT00978120
- NCT01654289
- NCT03629184
- NCT03684044
- NCT00908687
- NCT02623322
- NCT02287467
- NCT00958126
- NCT01014988
- NCT00419263
- NCT02814643
- NCT01949090
- NCT01825200
- NCT01050257
- NCT00545532
- NCT03615482
- NCT02839330
- NCT00957996

- NCT00719043
- NCT00616928
- NCT02290509
- NCT01033734
- NCT01359150
- NCT00996307
- NCT00952705
- NCT02469298
- NCT00993668
- NCT02124161
- NCT00946101
- NCT01954251
- NCT00952419
- NCT00952276
- NCT00972816
- NCT01310413
- NCT00953524
- NCT02464163
- NCT00976820
- NCT03481270
- NCT00979602
- NCT00001566
- NCT00985088
- NCT01044030
- NCT00345579
- NCT00973349
- NCT00289783
- NCT02289820
- NCT03262441
- NCT01249625
- NCT00950963
- NCT01767064
- NCT00312338
- NCT01175798
- NCT00710879
- NCT03457727
- NCT01000974
- NCT01179919
- NCT00336505
- NCT00345683
- NCT00129129
- NCT02190747
- NCT00359983
- NCT00205803
- NCT01048879
- NCT00413699
- NCT01978093
- NCT03281876
- NCT00148941
- NCT00197236
- NCT00739648
- NCT00373958
- NCT00100659
- NCT02155985
- NCT01102374
- NCT00336544
- NCT01000311
- NCT00377260
- NCT00814320
- NCT02534350
- NCT02135614
- NCT01949116
- NCT00806195
- NCT02643472
- NCT02165735
- NCT02096263
- NCT01012323
- NCT01814800
- NCT01218438
- NCT01659996
- NCT00640926
- NCT00772928
- NCT00474526
- NCT00802867
- NCT00621504
- NCT00483574
- NCT00422292
- NCT00384397
- NCT00546871
- NCT02499770
- NCT01881867
- NCT00710021
- NCT00509106
- NCT00930982
- NCT02446899
- NCT02446912
- NCT01173601

EudraCT Numbers:

- 2014-005053-40
- 2014-004543-12
- 2015-001258-13
- 2014-003768-19
- 2015-002973-39
- 2012-000218-12
- 2014-002599-95
- 2014-004248-36
- 2019-001974-27
- 2014-004498-17
- 2015-000175-27
- 2019-004721-24
- 2016-004753-33
- 2013-002081-39

Publications:

- Frenck, R. W., Jr, Belshe, R., Brady, R. C., Winokur, P. L., Campbell, J. D., Treanor, J., Hay, C. M., Dekker, C. L., Walter, E. B., Jr, Cate, T. R., Edwards, K. M., Hill, H., Wolff, M., Leduc, T., & Tornieporth, N. (2011). Comparison of the immunogenicity and safety of a split-virion, inactivated, trivalent influenza vaccine (Fluzone®) administered by intradermal and intramuscular route in healthy adults. *Vaccine*, 29(34), 5666–5674.
<https://doi.org/10.1016/j.vaccine.2011.06.010>
- Pavia-Ruz, N., Angel Rodriguez Weber, M., Lau, Y. L., Nelson, E. A., Kerdpanich, A., Huang, L. M., Silas, P., Qaqundah, P., Blatter, M., Jeanfreau, R., Lei, P., Jain, V., El Idrissi, M., Feng, Y., Innis, B., Peeters, M., & Devaster, J. M. (2013). A randomized controlled study to evaluate the immunogenicity of a trivalent inactivated seasonal influenza vaccine at two

- dosages in children 6 to 35 months of age. *Human vaccines & immunotherapeutics*, 9(9), 1978–1988. <https://doi.org/10.4161/hv.25363>
- Tsang, P., Gorse, G. J., Strout, C. B., Sperling, M., Greenberg, D. P., Ozol-Godfrey, A., DiazGranados, C., & Landolfi, V. (2014). Immunogenicity and safety of Fluzone(®) intradermal and high-dose influenza vaccines in older adults ≥ 65 years of age: a randomized, controlled, phase II trial. *Vaccine*, 32(21), 2507–2517. <https://doi.org/10.1016/j.vaccine.2013.09.074>
 - Jain, V. K., Domachowske, J. B., Wang, L., Ofori-Anyinam, O., Rodríguez-Weber, M. A., Leonardi, M. L., Klein, N. P., Schlichter, G., Jeanfreau, R., Haney, B. L., Chu, L., Harris, J. S., Sarpong, K. O., Micucio, A. C., Soni, J., Chandrasekaran, V., Li, P., & Innis, B. L. (2017). Time to Change Dosing of Inactivated Quadrivalent Influenza Vaccine in Young Children: Evidence From a Phase III, Randomized, Controlled Trial. *Journal of the Pediatric Infectious Diseases Society*, 6(1), 9–19. <https://doi.org/10.1093/jpids/piw068>
 - Athale, S., Banchereau, R., Thompson-Snipes, L., Wang, Y., Palucka, K., Pascual, V., & Banchereau, J. (2017). Influenza vaccines differentially regulate the interferon response in human dendritic cell subsets. *Science translational medicine*, 9(382), eaaf9194. <https://doi.org/10.1126/scitranslmed.aaf9194>
 - Statler, V. A., Albano, F. R., Airey, J., Sawlwin, D. C., Graves Jones, A., Matassa, V., Heijnen, E., Edelman, J., & Marshall, G. S. (2019). Immunogenicity and safety of a quadrivalent inactivated influenza vaccine in children 6-59 months of age: A phase 3, randomized, noninferiority study. *Vaccine*, 37(2), 343–351. <https://doi.org/10.1016/j.vaccine.2018.07.036>
 - Chang, L. J., Meng, Y., Janosczyk, H., Landolfi, V., Talbot, H. K., & QHD00013 Study Group (2019). Safety and immunogenicity of high-dose quadrivalent influenza vaccine in adults ≥ 65 years of age: A phase 3 randomized clinical trial. *Vaccine*, 37(39), 5825–5834. <https://doi.org/10.1016/j.vaccine.2019.08.016>