

Approval Date: [February 21, 2019](#)

Product: Zostavax®

Proper Name: Zoster Vaccine, Live

Indication: For prevention of herpes zoster (shingles) in individuals 50 years of age and older.

Description: ZOSTAVAX is a lyophilized preparation of the Oka/Merck strain of live, attenuated varicella-zoster virus (VZV). ZOSTAVAX, when reconstituted as directed, is a sterile suspension for subcutaneous administration.

BLA: 125123

Regulatory Milestone: No data available

PDUFA Goal Date: April 22, 2018

Package Insert:

- [Package Insert - Zostavax \(Frozen\)](#)
- [Package Insert - Zostavax \(Refrigerator Stable\)](#)
- [Patient Information - Zostavax \(Frozen\)](#)
- [Patient Information - Zostavax \(Refrigerator Stable\)](#)

Summary Basis for Regulatory Approval: [April 18, 2018 Summary Basis for Regulatory Action - ZOSTAVAX](#)

European Public Assessment Report: [EPAR Assessment Report](#)

Advisory Committee:

A Vaccines and Related Biologics Products Advisory Committee meeting was not held for this supplement as there were no issues or concerns that presented during the review of the supplement that required consult from the advisory committee.

Safety:

There were no safety concerns with the interim data in this supplement.

NCT Numbers: Completed Clinical Trials

- NCT01331161
- NCT02958345
- NCT01573182
- NCT03120364
- NCT03116594
- NCT01391546
- NCT00444860
- NCT00534248
- NCT00851786
- NCT01474720
- NCT01505647
- NCT01556451
- NCT01137669
- NCT01506661
- NCT02624375
- NCT01911065
- NCT03685682
- NCT01245751
- NCT00561080
- NCT01527370
- NCT00322231
- NCT00886613
- NCT02704572
- NCT00681031
- NCT00546819
- NCT00535730
- NCT02477150
- NCT03192319
- NCT02519855
- NCT00689013
- NCT02114333
- NCT00550745
- NCT00130793
- NCT02581410
- NCT01385566
- NCT00231816
- NCT01165229
- NCT00920218
- NCT02329457
- NCT00007501
- NCT01086449
- NCT01610414
- NCT01165203
- NCT01954251
- NCT00802464
- NCT00434577
- NCT02147587
- NCT00109122
- NCT01165177
- NCT01295320
- NCT01751165
- NCT02075515
- NCT01827839
- NCT02052596
- NCT02045836
- NCT01767467
- NCT03121638

- NCT01765413
- NCT01519570
- NCT01483378
- NCT02735915
- NCT02690207
- NCT01777321
- NCT01254630
- NCT01229267
- NCT01798056
- NCT00492648
- NCT02058589
- NCT02526745
- NCT02609035
- NCT03114982
- NCT03114943
- NCT02225327
- NCT02187055
- NCT02215863
- NCT00092417

EudraCT Numbers:

- 2007-000744-28
- 2007-006532-66
- 2007-000344-26
- 2007-004020-20
- 2005-003035-52
- 2009-012458-19
- 2006-003651-20
- 2007-000343-10
- 2014-000967-42
- 2009-014268-20
- 2014-000358-13

Publications:

- Hardy, I., Gershon, A. A., Steinberg, S. P., & LaRussa, P. (1991). The incidence of zoster after immunization with live attenuated varicella vaccine. A study in children with leukemia. *Varicella Vaccine Collaborative Study Group. The New England journal of medicine*, 325(22), 1545–1550. <https://doi.org/10.1056/NEJM199111283252204>
- Oxman, M. N., Levin, M. J., Johnson, G. R., Schmader, K. E., Straus, S. E., Gelb, L. D., Arbeit, R. D., Simberkoff, M. S., Gershon, A. A., Davis, L. E., Weinberg, A., Boardman, K. D., Williams, H. M., Zhang, J. H., Peduzzi, P. N., Beisel, C. E., Morrison, V. A., Guatelli, J. C., Brooks, P. A., Kauffman, C. A., ... Shingles Prevention Study Group (2005). A vaccine to prevent herpes zoster and postherpetic neuralgia in older adults. *The New England journal of medicine*, 352(22), 2271–2284. <https://doi.org/10.1056/NEJMoa051016>
- Gilderman, L. I., Lawless, J. F., Nolen, T. M., Sterling, T., Rutledge, R. Z., Fernsler, D. A., Azrolan, N., Sutradhar, S. C., Wang, W. W., Chan, I. S., Schlienger, K., Schödel, F., Silber, J. L., & Zostavax Protocol 010 Study Group (2008). A double-blind, randomized, controlled, multicenter safety and immunogenicity study of a refrigerator-stable

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<https://doi.org/10.1128/CVI.00310-07>

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- Gershon, A. A., Levin, M. J., Weinberg, A., Song, L. Y., LaRussa, P. S., Steinberg, S. P., Bartlett, P., & Pediatric AIDS Clinical Trials Group 391 Team (2009). A phase I-II study of live attenuated varicella-zoster virus vaccine to boost immunity in human immunodeficiency virus-infected children with previous varicella. *The Pediatric infectious disease journal*, 28(7), 653–655.
<https://doi.org/10.1097/INF.0b013e3181998f06>
- Gershon, A. A., Levin, M. J., Weinberg, A., Song, L. Y., LaRussa, P. S., Steinberg, S. P., Bartlett, P., & Pediatric AIDS Clinical Trials Group 391 Team (2009). A phase I-II study of live attenuated varicella-zoster virus vaccine to boost immunity in human immunodeficiency virus-infected children with previous varicella. *The Pediatric infectious disease journal*, 28(7), 653–655.
<https://doi.org/10.1097/INF.0b013e3181998f06>
- Schmader, K. E., Levin, M. J., Gnann, J. W., Jr, McNeil, S. A., Vesikari, T., Betts, R. F., Keay, S., Stek, J. E., Bundick, N. D., Su, S. C., Zhao, Y., Li, X., Chan, I. S., Annunziato, P. W., & Parrino, J. (2012). Efficacy, safety, and tolerability of herpes zoster vaccine in persons aged 50-59 years. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*, 54(7), 922–928.
<https://doi.org/10.1093/cid/cir970>
- Vesikari, T., Hardt, R., Rümke, H. C., Icardi, G., Montero, J., Thomas, S., Sadorge, C., & Fiquet, A. (2013). Immunogenicity and safety of a live attenuated shingles (herpes zoster) vaccine (Zostavax®) in individuals aged ≥ 70 years: a randomized study of a single dose vs. two different two-dose schedules. *Human vaccines & immunotherapeutics*, 9(4), 858–864. <https://doi.org/10.4161/hv.23412>
- Gilbert, P. B., Gabriel, E. E., Miao, X., Li, X., Su, S. C., Parrino, J., & Chan, I. S. (2014). Fold rise in antibody titers by measured by glycoprotein-based enzyme-linked

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- Diez-Domingo, J., Weinke, T., Garcia de Lomas, J., Meyer, C. U., Bertrand, I., Eymin, C., Thomas, S., & Sadorge, C. (2015). Comparison of intramuscular and subcutaneous administration of a herpes zoster live-attenuated vaccine in adults aged ≥ 50 years: a randomised non-inferiority clinical trial. *Vaccine*, 33(6), 789–795. <https://doi.org/10.1016/j.vaccine.2014.12.024>
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