

**Approval Date:** [April 23, 2020](#)

**Product:** MenQuadfi

**Proper Name:** Meningococcal (Groups A, C, Y, W) Conjugate Vaccine

**Manufacturer:** Sanofi Pasteur, Inc.

**Indication:** Meningococcal (Groups A, C, Y, W) Conjugate Vaccine is indicated for active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y. Meningococcal (Groups A, C, Y, W) Conjugate Vaccine is approved for use in individuals 2 years of age and older.

**Description:** MenQuadfi is a sterile liquid vaccine administered by intramuscular injection that contains *Neisseria meningitidis* serogroup A, C, W, and Y capsular polysaccharide antigens that are individually conjugated to tetanus toxoid protein.

**BLA:** 125701

**Regulatory Milestone:** None

**PDUFA Goal Date:** April 24, 2020

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

**Summary Basis for Regulatory Approval:** [April 22, 2020 Summary Basis for Regulatory Action - MenQuadfi](#)

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

**Advisory Committee:**

An Advisory Committee Meeting for MenQuadfi vaccine was not held because there were no issues pertaining to this BLA that required input from the Vaccines and Related Biological Products Advisory Committee.

**NCT Numbers:**

- NCT03869866
- NCT04490018
- NCT01897402
- NCT01732627
- NCT01482052
- NCT02640404
- NCT01270503
- NCT03077438
- NCT01519713
- NCT01642589
- NCT02842866
- NCT02842853
- NCT01359449
- NCT02752906
- NCT04368429
- NCT02591290
- NCT02864927
- NCT02699840
- NCT00384397
- NCT02003495
- NCT00444951
- NCT01890759
- NCT00422292
- NCT00874549
- NCT02955797
- NCT00700713
- NCT00901940
- NCT01659996
- NCT03630705
- NCT00700635
- NCT04236960
- NCT01682876
- NCT03295318
- NCT02633787
- NCT01823536
- NCT02199691
- NCT04084769
- NCT01086969
- NCT03205358
- NCT01148017
- NCT01430689
- NCT03691610
- NCT00254995
- NCT00728260
- NCT00483574
- NCT00777257
- NCT03547271
- NCT03632720
- NCT02986854
- NCT02481232
- NCT04490018
- NCT04142242
- NCT00119080
- NCT03537508
- NCT03205371
- NCT01272180
- NCT03890367
- NCT00772629
- NCT00771849
- NCT01442675
- NCT04358731
- NCT00777790
- NCT01367158
- NCT00355121
- NCT00539032
- NCT01973218
- NCT00282295
- NCT01239043
- NCT04626297

**EudraCT Numbers:**

- 2018-001471-20
- 2018-001468-48
- 2016-000749-30
- 2016-001963-35
- 2009-016841-24
- 2016-003186-25

- 2015-001030-16
- 2016-002381-31
- 2011-000476-34
- 2007-007837-38
- 2012-003937-41
- 2011-000475-14
- 2013-002451-15
- 2014-004537-95
- 2014-005161-72
- 2014-005392-90
- 2014-004492-23
- 2006-006680-23
- 2016-002230-69

**Publications:**

- Meningococcal Vaccines. (2020). In Drugs and Lactation Database (LactMed). National Library of Medicine (US).
- In Brief: New meningococcal serogroup B vaccination recommendations. (2020). The Medical letter on drugs and therapeutics, 62(1612), 191–192.
- Keyserling, H., Papa, T., Koranyi, K., Ryall, R., Bassily, E., Bybel, M. J., Sullivan, K., Gilmet, G., & Reinhardt, A. (2005). Safety, immunogenicity, and immune memory of a novel meningococcal (groups A, C, Y, and W-135) polysaccharide diphtheria toxoid conjugate vaccine (MCV-4) in healthy adolescents. Archives of pediatrics & adolescent medicine, 159(10), 907–913. <https://doi.org/10.1001/archpedi.159.10.907>
- Lagos, R., Papa, T., Muñoz, A., Ryall, R., Pina, M., & Bassily, E. (2005). Safety and immunogenicity of a meningococcal (Groups A, C, Y, W-135) polysaccharide diphtheria toxoid conjugate vaccine in healthy children aged 2 to 10 years in Chile. Human vaccines, 1(6), 228–231. <https://doi.org/10.4161/hv.1.6.2301>
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- Robertson, C. A., Greenberg, D. P., Hedrick, J., Pichichero, M., Decker, M. D., & Saunders, M. (2016). Safety and immunogenicity of a booster dose of meningococcal (groups A, C, W,

and Y) polysaccharide diphtheria toxoid conjugate vaccine. *Vaccine*, 34(44), 5273–5278.

<https://doi.org/10.1016/j.vaccine.2016.09.003>

- Fukushima, S., Kikuchi, H., Miyazu, M., Hamada, A., Ouchi, K., Takagi, H., Mihara, H., Sasaki, T., Oka, H., Bosch-Castells, V., & Oster, P. (2018). A Safety and Immunogenicity Study of a Single Dose of a Meningococcal (Groups A, C, W, and Y) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (MEN-ACWY-D) in Healthy Japanese Participants. *Japanese journal of infectious diseases*, 71(6), 402–407.  
<https://doi.org/10.7883/yoken.JJID.2017.277>
- Matsuoka, O., Tsuzuki, D., Suzuki, K., Tanaka, T., Takagi, Y., & Oster, P. (2020). Immunogenicity and Safety of a Two-Dose Series of a Meningococcal (Groups A, C, W, and Y) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (MEN ACWY-D) in Healthy Japanese Adults. *Japanese journal of infectious diseases*, 10.7883/yoken.JJID.2020.411. Advance online publication. <https://doi.org/10.7883/yoken.JJID.2020.411>