Approval Date: September 25, 2020

Product: PNEUMOVAX® 23

Proper Name: Pneumococcal Vaccine, Polyvalent

Manufacturer: Merck Sharp & Dohme Corporation

Indication: For active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F) in persons 50 years of age or older and persons aged ≥2 years who are at increased risk for pneumococcal disease.

Description of Product: PNEUMOVAX 23 consist of a mixture of purified capsular polysaccharides from Streptococcus pneumoniae types (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, and 33F).

BLA: 101094

Regulatory Milestone: No data available

PDUFA Goal Date: October 27, 2011

Package Insert: Package Insert - Pneumovax 23

Summary Basis for Regulatory Approval: Summary Basis for Regulatory Action - Pneumovax 23 - October 25, 2011

Summary for Basis of Approval - PNEUMOVAX-23 - Pneumococcal Vaccine, PolyValent, June 30, 1983

European Public Assessment Report: Prevenar 13 : EPAR - Public assessment report

Advisory Committee: There were no issues in this supplement that required input from an Advisory Committee.

Safety: No new safety concerns were identified

NCT Numbers:

- NCT02471014
- NCT02097589
- NCT03260790
- NCT01307449
- NCT01974817
- NCT02719379
- NCT00323557
- NCT01944462
- NCT00479323
- NCT00589394
- NCT00706550
- NCT00824850
- NCT00169234
- NCT02558751
- NCT01128439
- NCT03802994
- NCT03039491
- NCT00205803
- NCT00164411
- NCT02955160
- NCT01852591
- NCT00304382
- NCT00133549
- NCT00829595
- NCT00445484
- NCT00239694
- NCT00741039
- NCT02515240
- NCT00955851
- NCT00294021
- NCT02543918
- NCT00569309
- NCT00617682
- NCT01349569
- NCT00153543
- NCT01128426
- NCT03642847
- NCT01239875
- NCT01245673
- NCT01660529
- NCT02079701
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- NCT01467934
- NCT01537185
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- NCT02231957
- NCT01083459
- NCT00499577
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- NCT00359983
- NCT00345683
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EudraCT Numbers:

- 2014-003007-29
- 2006-000560-93
- 2007-000344-26
- 2017-004024-30
- 2012-005314-19
- 2017-001909-32
- 2011-004542-18
- 2014-004013-85
- 2008-001282-28
- 2015-001656-29
- 2005-003052-36
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- 2017-004915-38
- 2019-000341-12
- 2019-001118-40
- 2020-002850-26
- 2018-000066-11
- 2008-007605-37
- 2014-001118-24
- 2010-022205-17
- 2005-005682-11

Publications:

- Leroux-Roels, G., Maes, C., De Boever, F., Traskine, M., Rüggeberg, J. U., & Borys, D. (2014). Safety, reactogenicity and immunogenicity of a novel pneumococcal protein-based vaccine in adults: a phase I/II randomized clinical study. *Vaccine*, *32*(50), 6838–6846. https://doi.org/10.1016/j.vaccine.2014.02.052
- Parker, A. R., Bradley, C., Harding, S., Sánchez-Ramón, S., Jolles, S., & Kiani-Alikhan, S. (2018). Measurement and interpretation of Salmonella typhi Vi IgG antibodies for the assessment of adaptive immunity. *Journal of immunological methods*, *459*, 1–10. https://doi.org/10.1016/j.jim.2018.05.013