PNEUMOVAX 23 is recommended by the CDC for all your appropriate adult patients at increased risk for pneumococcal disease[1,2]:

Adults aged <65 years with certain chronic conditions including:

Diabetes mellitus
Chronic heart disease
Chronic lung disease[a]

Adults aged ≥65 years as part of a 2-vaccine regimen

Please see CDC Sequential Dosing Recommendation Guide (inside).

PNEUMOVAX 23 is a vaccine indicated 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).

PNEUMOVAX 23 is approved for use in persons 50 years of age or older and persons aged ≥2 years who are at increased risk for pneumococcal disease.

PNEUMOVAX 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

Select Safety Information

Do not administer PNEUMOVAX 23 to individuals with a history of a hypersensitivity reaction to any component of the vaccine.

Defer vaccination with PNEUMOVAX 23 in persons with moderate or severe acute illness.

[a]Includes chronic obstructive pulmonary disease (COPD).
CDC=Centers for Disease Control and Prevention.

PNEUMOVAX®23
(Pneumococcal Vaccine Polyvalent)

Adult patients aged <65 years:

The CDC specifically recommends 1 dose of PNEUMOVAX 23 for appropriate adults with certain chronic conditions, including diabetes mellitus, chronic heart disease, and chronic lung disease (COPD), at the time of diagnosis[1]

Compared to healthy adults of the same age, these patients have a **higher risk** for invasive pneumococcal disease (IPD)[3,a]

Not actual patients.

[a]Retrospective cohort study (adults aged 18–64 years) using data from January 1, 2006, through December 31, 2010, from 3 health care claims databases representing >35 million insured adults. Risk for IPD was compared to age-matched healthy counterparts.

Multiple professional organizations are consistent with the CDC's recommendation of pneumococcal vaccination for appropriate adults with certain chronic conditions[1,4–6]

DIABETES MELLITUS
American Diabetes Association

CHRONIC HEART DISEASE
American Heart Association
American College of Cardiology

COPD
Global Initiative for Chronic Obstructive Lung Disease

Select Safety Information *(continued)*

Use caution and appropriate care in administering PNEUMOVAX 23 to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

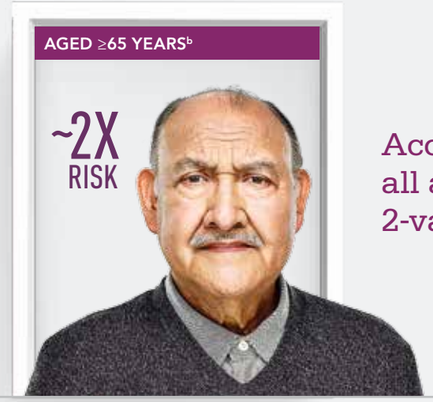
PNEUMOVAX 23 should be given to a pregnant woman only if clearly needed.

Immunocompetent patients aged ≥65 years:

The CDC recommends that appropriate adults receive PNEUMOVAX 23 as part of a sequential administration of 2 pneumococcal vaccines[2,7,*]

*Pneumococcal vaccination history will determine the use of each vaccine in this patient population. Please see **CDC Sequential Dosing Recommendation Guide inside.**

Compared to healthy adults aged 50–64 years, healthy patients aged ≥65 years have a **higher risk** for invasive pneumococcal disease (IPD)[3,b]



According to the updated CDC recommendations, all adults aged ≥65 years should receive a 2-vaccine regimen of PCV13 and PNEUMOVAX 23[7,*]

[b]Retrospective cohort study using data from January 1, 2006, through December 31, 2010, from 3 health care claims databases representing >35 million insured adults ≥18 years of age. Rates of IPD were compared between healthy adults ≥65 years of age and healthy adults 50 to 64 years of age.

Select Safety Information

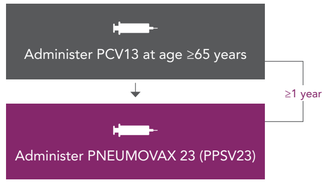
Caution should be exercised when PNEUMOVAX 23 is administered to a nursing woman.

Since elderly individuals may not tolerate medical interventions as well as younger individuals, a higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out.

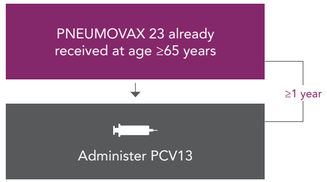
PNEUMOVAX®23
(Pneumococcal Vaccine Polyvalent)

CDC-recommended sequential administration and intervals for immunocompetent adults aged ≥65 years[7,a,b]

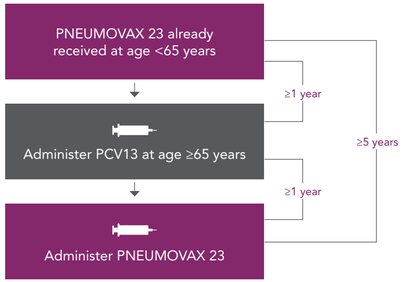
Pneumococcal vaccine-naïve persons aged ≥65 years



Persons who previously received PNEUMOVAX 23 at age ≥65 years



Persons who previously received PNEUMOVAX 23 before age 65 years who are now aged ≥65 years



PCV13=13-valent pneumococcal conjugate vaccine.
PPSV23=23-valent pneumococcal polysaccharide vaccine.

[a]If a dose of PNEUMOVAX 23 is given earlier than the recommended interval, the dose need not be repeated.
[b]PNEUMOVAX 23 and PCV13 should not be coadministered.

Important considerations:

- There are limited data on the sequential administration of PNEUMOVAX 23 with other vaccines, including PCV13.
- An immunogenicity study described in the Prescribing Information for PCV13 evaluated the sequential administration with PNEUMOVAX 23 in adults aged 60–64 years[8]:
  - Diminished immune response with one dose of PNEUMOVAX 23 followed by a dose of PCV13 one year later vs PCV13 alone
  - Noninferior immune response with one dose of PCV13 followed by a dose of PNEUMOVAX 23 one year later vs PNEUMOVAX 23 alone
- The levels of antibodies that correlate with protection against pneumococcal disease have not been clearly defined.
- Routine revaccination of immunocompetent persons previously vaccinated with a 23-valent vaccine is not recommended.
- For subjects aged ≥65 years in a clinical study, systemic adverse reactions which were determined by the investigator to be vaccine-related were higher following revaccination with PNEUMOVAX 23 than following initial vaccination with PNEUMOVAX 23.

Select Safety Information *(continued)*

Persons who are immunocompromised, including persons receiving immunosuppressive therapy, may have a diminished immune response to PNEUMOVAX 23.

PNEUMOVAX 23 may not be effective in preventing pneumococcal meningitis in patients who have chronic cerebrospinal fluid (CSF) leakage resulting from congenital lesions, skull fractures, or neurosurgical procedures.

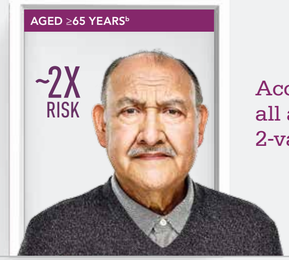
For subjects aged 65 years or older in a clinical study, systemic adverse reactions which were determined by the investigator to be vaccine-related were higher following revaccination than following initial vaccination.

Immunocompetent patients aged ≥65 years:

The CDC recommends that appropriate adults receive PNEUMOVAX 23 as part of a sequential administration of 2 pneumococcal vaccines[2,7,*]

*Pneumococcal vaccination history will determine the use of each vaccine in this patient population. Please see **CDC Sequential Dosing Recommendation Guide inside.**

Compared to healthy adults aged 50–64 years, healthy patients aged ≥65 years have a **higher risk** for invasive pneumococcal disease (IPD)[3,b]



According to the updated CDC recommendations, all adults aged ≥65 years should receive a 2-vaccine regimen of PCV13 and PNEUMOVAX 23[7,*]

[b]Retrospective cohort study using data from January 1, 2006, through December 31, 2010, from 3 health care claims databases representing >35 million insured adults ≥18 years of age. Rates of IPD were compared between healthy adults ≥65 years of age and healthy adults 50 to 64 years of age.

Select Safety Information

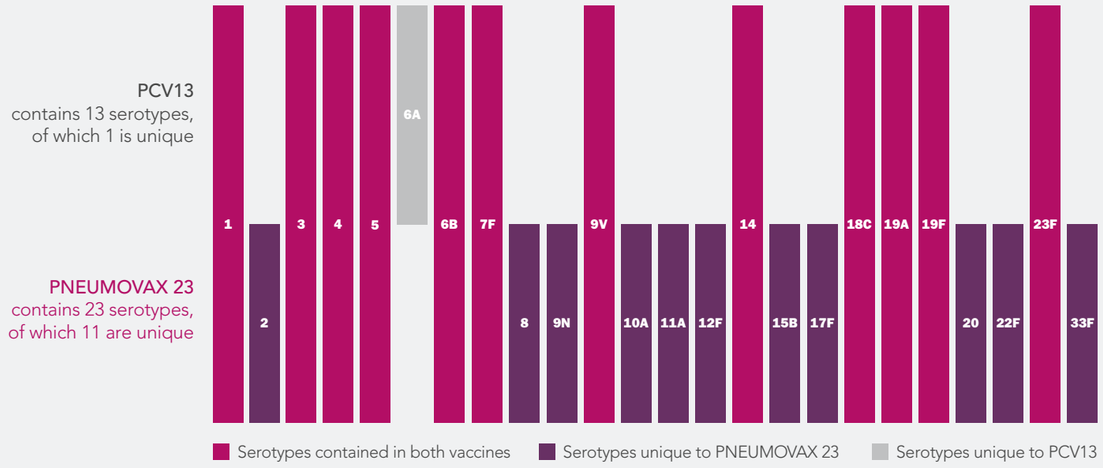
Caution should be exercised when PNEUMOVAX 23 is administered to a nursing woman.

Since elderly individuals may not tolerate medical interventions as well as younger individuals, a higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out.

PNEUMOVAX 23
(Pneumococcal Vaccine Polyvalent)

Different serotypes can cause pneumococcal disease—
PNEUMOVAX 23 is the only pneumococcal vaccine indicated to prevent disease caused by 23 serotypes[8]

Serotypes contained in PCV13 and PNEUMOVAX 23[8]



PCV13=13-valent pneumococcal conjugate vaccine.

PNEUMOVAX 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

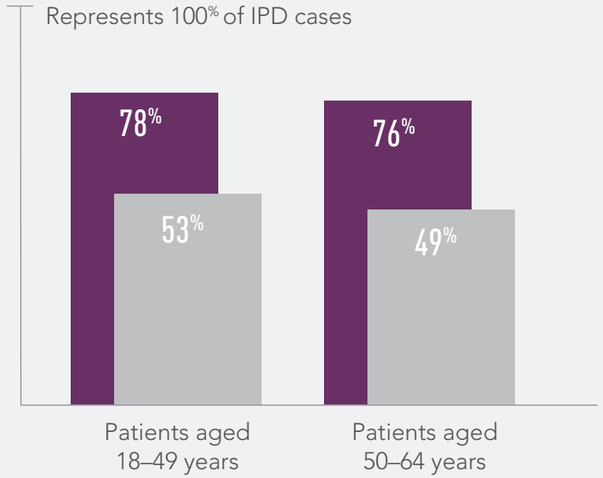
Select Safety Information *(continued)*

The most common adverse reactions, reported in >10% of subjects vaccinated with PNEUMOVAX 23 in clinical trials, were: injection-site pain/soreness/tenderness, injection-site swelling/induration, headache, injection-site erythema, asthenia and fatigue, and myalgia.

Vaccination with PNEUMOVAX 23 may not offer 100% protection from pneumococcal infection.

In patients aged <65 years

Percentage of all IPD cases caused by serotypes in each vaccine—United States, 2008[9]



The serotypes in PNEUMOVAX 23 accounted for ~25% more IPD cases compared to the percentage of IPD cases caused by serotypes in PCV13.

The figure depicts CDC epidemiologic data and does not reflect the efficacy of the respective vaccines.

In patients aged ≥65 years

~40% of IPD was caused by the 11 unique serotypes in PNEUMOVAX 23, according to the CDC in 2013.[7]

Select Safety Information

Do not administer PNEUMOVAX 23 to individuals with a history of a hypersensitivity reaction to any component of the vaccine.

Defer vaccination with PNEUMOVAX 23 in persons with moderate or severe acute illness.

PNEUMOVAX 23
(Pneumococcal Vaccine Polyvalent)

In a 14-year retrospective study,
PNEUMOVAX 23 demonstrated reduction of disease in adults[10,a]

Effectiveness demonstrated against invasive pneumococcal infections caused by serotypes in the vaccine[10,a,b]

57% Overall in all populations (n=2,837)

Diabetes Mellitus	Coronary Vascular Disease	Congestive Heart Failure	Chronic Pulmonary Disease	Aged ≥65 years (immunocompetent)
84%	73%	69%	65%	75%

[a]Effectiveness was evaluated using the 14- and 23-capsular pneumococcal polysaccharide vaccine.
[b]Vaccine effectiveness could not be confirmed for certain groups of immunocompromised patients.

Study Design: A US retrospective, indirect cohort study covering a 14-year period (1978–1992), in 54 hospitals, and 26 states. Patients eligible for inclusion were ≥2 years of age with a known vaccination status/date, who were monitored for illness during this period, and from whom pneumococcus was isolated from blood or cerebrospinal fluid (CSF). The median age of vaccinated patients was 57 years; the median age of unvaccinated was 50 years. Vaccine effectiveness was estimated by comparing the distribution of disease-causing pneumococcal serotypes in vaccinated (eg, received either the 14-valent or 23-valent pneumococcal polysaccharide vaccines) and unvaccinated persons. Vaccine effectiveness was also estimated for study participants with underlying medical conditions.[10]

Not an actual patient.

Select Safety Information *(continued)*

Use caution and appropriate care in administering PNEUMOVAX 23 to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

PNEUMOVAX 23 should be given to a pregnant woman only if clearly needed.

Select Safety Information

Caution should be exercised when PNEUMOVAX 23 is administered to a nursing woman.

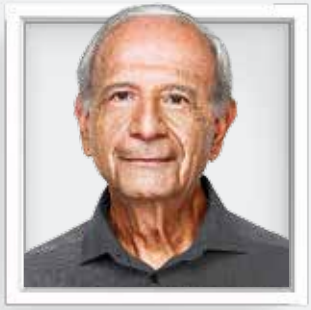
Since elderly individuals may not tolerate medical interventions as well as younger individuals, a higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out.

PNEUMOVAX®23
(Pneumococcal Vaccine Polyvalent)

Keep in mind the CDC recommendations for PNEUMOVAX 23 for all appropriate adults[1,7]:

Not actual patients.

Adults aged <65 years with certain chronic conditions, including diabetes mellitus, chronic heart disease, and chronic lung disease (COPD): Vaccinate with 1 dose of PNEUMOVAX 23 at time of diagnosis.[1]



Immunocompetent adults aged ≥65 years: Vaccinate appropriate patients with PNEUMOVAX 23 as part of a 2-vaccine sequential regimen. Please see CDC Sequential Dosing Recommendation Guide (inside).[7]

PNEUMOVAX 23 is a vaccine indicated 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).

PNEUMOVAX 23 is approved for use in persons 50 years of age or older and persons aged ≥2 years who are at increased risk for pneumococcal disease.

PNEUMOVAX 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

Select Safety Information *(continued)*

Persons who are immunocompromised, including persons receiving immunosuppressive therapy, may have a diminished immune response to PNEUMOVAX 23.

Vaccination with PNEUMOVAX 23 may not offer 100% protection from pneumococcal infection.

Before administering PNEUMOVAX 23, please read the accompanying Prescribing Information. The Patient Information also is available.

For additional copies of the Prescribing Information, please call 800-672-6372, visit MerckVaccines.com®, or contact your Merck representative.

References: 1. Centers for Disease Control and Prevention (CDC). Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine for adults with immunocompromising conditions: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 2012;61(40):816–819. **2.** Centers for Disease Control and Prevention (CDC). Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 2014;63(37):822–825. **3.** Shea KM, Edelsberg J, Weycker D, et al. Rates of pneumococcal disease in adults with chronic medical conditions. *Open Forum Infect Dis*. 2014;1(1):1–9. **4.** American Diabetes Association. Standards of medical care in diabetes—2016. *Diabetes Care*. 2016;39(suppl 1):S1–S112. **5.** Amsterdam EA, Wenger NK, Brindis RG, et al. 2014 AHA/ACC Guideline for the Management of Patients With Non–ST-Elevation Acute Coronary Syndromes. *J Am Coll Cardiol*. 2014;64(24):e139–e228. **6.** Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Updated 2016. http://www.goldcopd.org/guidelines-global-strategy-for-diagnosis-management.html. Accessed February 1, 2016. **7.** Centers for Disease Control and Prevention (CDC). Intervals between PCV13 and PPSV23 vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep*. 2015;64(34):944–947. (Erratum Notice: CDC. *MMWR Morb Mortal Wkly Rep*. 2015;64(42):1204.) **8.** Prevnar 13 [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; 2015. **9.** Centers for Disease Control and Prevention (CDC); Advisory Committee on Immunization Practices. Updated recommendations for prevention of invasive pneumococcal disease among adults using the 23-valent pneumococcal polysaccharide vaccine (PPSV23). *MMWR Morb Mortal Wkly Rep*. 2010;59(34):1102–1106. **10.** Butler JC, Breiman RF, Campbell JF, et al. Pneumococcal polysaccharide vaccine efficacy: an evaluation of current recommendations. *JAMA*. 1993;270(15):1826–1831.

PNEUMOVAX®23
(Pneumococcal Vaccine Polyvalent)

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