Prevenar 13®

Pneumococcal polysaccharide Conjugate Vaccine (Adsorbed) Ph. Eur., 13-valent

Most widely used PCV in the world[2,3]

PCV: Pneumococcal Conjugate Vaccine

References:

1. Jayaraman Y, Veeraraghavan B, Purushothaman GK, et.al. Burden of bacterial meningitis in India: Preliminary data from a hospital based sentinel surveillance network. PloS one. 2018 May 16;13(5):e0197198.
2. Johns Hopkins Bloomberg School of Public Health – IVAC: Interactive Vaccines Access Center (View-Hub) data. Oct-17. https://www.jhsph.edu/research/centers-and-institutes/ivac/view-hub/index.html. [Last accessed January 30, 2019].
3. Data on file. Pfizer Inc, New York, NY. 2018.

Balancing Risk Information:

Prevenar 13 does not provide 100% protection against vaccine serotypes, or protect against nonvaccine serotypes. The approval of Prevenar13 was based upon functional antibody responses in adults 50 years and older. Prevenar13 has not been shown to reduce morbidity or mortality due to pneumococcal disease/invasive pneumococcal disease in adults. The most commonly reported solicited local and systemic adverse reactions (~20%) in clinical trials with Prevenar13 were redness, swelling, tenderness, hardness, and pain at the injection site, limitation of arm movement, decreased appetite, headache, diarrhea, chills, fatigue, rash, and worsening of or new joint or muscle pain. Hypersensitivity (eg, anaphylaxis) to any component of Prevenar13 or any diphtheria toxoid-containing vaccine is a contraindication to the use of Prevenar13. Antimicrobial resistance rates vary by region and from country to country. In the pre-2008 clinical studies, the pre-2008 Clinical and Laboratory Standards Institute (CLSI) antibacterial minimum inhibitory concentrations interpretive criteria were used to determine susceptibility to penicillin. These older thresholds may overestimate what current resistance rates may be. Measures of immune responses to Prevenar 13 reflect the study population and do not necessarily predict protection in an individual. The antibody threshold that correlates with protection against pneumococcal disease/invasive pneumococcal disease in adults has not been determined for any serotype Memory B cell production has not been studied with Prevenar13 in adults. The frequency of pneumococcal serotypes and serogroups can vary from country to country, which could influence the effectiveness of vaccination in any given country. Since serotypes other than those contained in the vaccine may contribute to the burden of pneumococcal disease/invasive pneumococcal disease, protection against all pneumococcal disease/invasive pneumococcal disease should not be expected. When compared with a nonconjugated pneumococcal polysaccharide vaccine (PPSV) in pivotal clinical trials, Prevenar13 demonstrated a noninferior functional antibody response (primary end point) for all shared serotypes, and the immune response to 6A achieved predetermined study thresholds for superiority. Pivotal Phase 3 studies were not powered to detect differences in the immune responses between healthy adults and those with specific stable, chronic comorbidities. Prevenar13 is approved for use in children from 6 weeks to 5 years of age and adults of 50 years of age and above. Pfizer India does not promote or support its use in any other age group, in any way.

Summary of Prescribing Information:

Composition: Pneumococcal 13 - valent conjugate vaccine (Diphtheria CRM197 Protein) is a sterile solution of saccharides of the capsular antigens of Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F individually conjugated to diphtheria CRM197 protein. Indications: In infants and children from 2 months to 5 years of age, Prevenar 13 is indicated for active immunization for the prevention of disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F (including sepsis, meningitis, bacteraemia, pneumonia and acute otitis media); In adults of 50 years and older age group, Prevenar 13 is indicated for active immunization for theprevention of pneumonia and invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F. Contraindications: Hypersensitivity to any component of the vaccine, or to diphtheria toxoid. Adverse reactions: In pediatric population: decreased appetite, irritability, drowsiness/increased sleep, restless sleep/decreased sleep, fever, any injection-site erythema, induration/swelling or pain/tenderness. In adult population: The safety of Prevenar 13 was assessed in 6 clinical studies, which included 6,198 adults (5,667 received Prevenar13) ranging in age from 50 through 95 years. Pain, redness, swelling and limitation of arm movement were observed locally; generalized muscle and joint pains, fatigue, headache, rash, chills, vomiting, decreased appetite, fever have been observed. Across the 6 studies, serious adverse events within 1 month of vaccination were reported after an initial study dose in 0.2%-1.4% of 5055 persons vaccinated with Prevenar 13 and in 0.4%-1.7% of 1124 persons vaccinated after an initial study dose of PPSV23. From 1 month to 6 months after an initial study dose, serious adverse events were reported in 1.2%-5.8% of persons Vaccinated during the studies with Prevenar 13 and in 2.4%-5.5% of persons vaccinated with PPSV23. One case of erythema multiforme occurred 34 days after receipt of a second dose of Prevenar 13. Concomitant administration with TIV may lead to an increase in some non-serious systemic adverse reactions. Warnings and Precautions: Prevenar 13 will only protect against pneumococcal serotypes included in the vaccine, and may not protect all individuals receiving the vaccine. Safety and immunogenicity data on Prevenar 13 are not available for immunocompromised individuals (e.g., individuals with splenic dysfunction, HIV infection, malignancy, nephrotic syndrome) and vaccination should be considered on an individual basis. Premature infants may suffer from apnea after primary immunization series. Very premature infants (born <30 weeks of gestation) may require monitoring for at least 48 hours after vaccination. Different injectable vaccines should always be given at different injection sites. The safety and immunogenicity for other routes (e.g. subcutaneous) have not been evaluated. Dosage: For infants, the immunization series of Prevenar13 consists of three doses of 0.5ml each at approximately 2-month intervals, followed by a fourth dose of 0.5 ml at 12-15 months of age. The customary age for the first dose is 2 months of age, but it can be given as young as 6 weeks of age. The recommended dosing interval is 4 to 8 weeks. The fourth dose should be administered at least 2 months after the third dose. For adults 50 years of age and older, Prevenar13 is to be administered as a single dose, including for those previously vaccinated with a pneumococcal polysaccharide vaccine. The need for re-vaccination with a subsequent dose of Prevenar13 has not been established. Administration: 00.5 mL/dose intramuscularly. Prevenar13 is available as a pre-filled syringe. The preferred sites are the anterolateral aspect of the thigh in infants or the deltoid muscle of the upper arm in older children and adults. Storage: Prevenar 13 should not be frozen. Store in a refrigerated place, away from the freezer compartment, at 2oC to 8oC (36oF to 46oF). Discard if the vaccine has been frozen. Parenteral products should be inspected visually for particulate matter or discoloration prior to use.

Full prescribing Information available on request
Prevenar 13 SPC adapted From LPDPRV032015 Version 10.0
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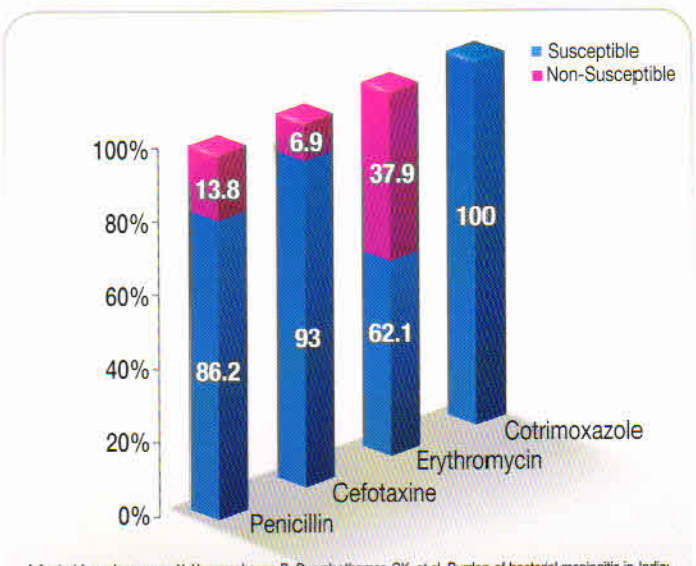
PP-PNP-IND-0258 March 28th 2019

For the use of Registered Medical Practitioner or Hospital or Laboratory.

S. pneumoniae is the commonest cause of bacterial meningitis in hospitalized children under 5 years of age in India[1]

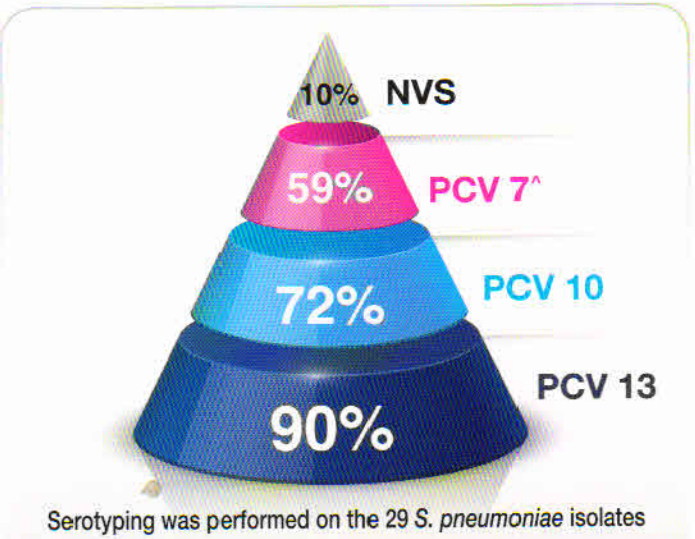
Meningitis was due to ***S. pneumoniae* 82.9%** (213/257), **Hib 14.4%** (37/257) **and N. meningitidis 2.7%** (7/257)[1*]

Highest prevalence 55.3% (142 out of 257) was observed among **children of 1 to 11 months** of age[1*]



Adapted from Jayaraman Y, Veeraraghavan B, Purushothaman GK, et.al. Burden of bacterial meningitis in India: Preliminary data from a hospital based sentinel surveillance network. PloS one. 2018 May 16;13(5):e0197198.

Antimicrobial Susceptibility Testing Revealed that all 29 Isolates Showed Resistance to Commonly Used Antibiotics[1]



Serotyping was performed on the 29 *S. pneumoniae* isolates

Adapted from Jayaraman Y, Veeraraghavan B, Purushothaman GK, et.al. Burden of bacterial meningitis in India: Preliminary data from a hospital based sentinel surveillance network. PloS one. 2018 May 16;13(5):e0197198.

Pneumococcal Serotypes Covered by PCVs[1]

* Based on an article that assessed Preliminary data from a hospital based sentinel surveillance network. See Summary of Prescribing Information on last page.

NVS: Non-vaccine serotype. PCV: Pneumococcal conjugate vaccine.
^PCV7 is no longer marketed and has been replaced by PCV13.

INDIAN SOCIETY OF NEPHROLOGY GUIDELINES FOR VACCINATION IN CHRONIC KIDNEY DISEASE

Adapted from: INDIAN JOURNAL OF NEPHROLOGY
Vol. 26, Supplement 1 – 2016 | www.indianjnephrol.org

1. The burden of **pneumococcal infections in CKD patients is high.**[1]

2. The **cost of pneumococcal vaccination is low** as compared with the global health costs in this population, and there are no data indicating potential disadvantages.[1]

3. Thus, **pneumococcal vaccination should be administered to all patients with CKD** as early in the disease as possible.[1]

Guidelines for administering PCV13 and PPSV23 vaccines for patients with chronic kidney disease:[2]

Vaccine history	Recommended regimen		
Infants & children (ages 0-18 years)			
Never vaccinated with PCV7 or PCV13 up to age	Routine vaccination for PCV13 (4 dose series)	Administer 1 dose of PPSV23 at age ≥2 years and ≥8 weeks after last indicated dose of PCV13	Administer 1 dose of PPSV23 after 5 years
Completed all recommended doses of PCV7	Administer 1 dose of PCV13 ≥8 weeks later	Administer 1 dose of PPSV23 at age ≥2 years and ≥8 weeks after last indicated dose of PCV13	Administer 1 dose of PPSV23 after 5 years
Children aged 24-71 months who received <3 doses of PCV7 before age 24 months	Administer 2 doses of PCV13 now	Administer 1 dose of PPSV23 ≥8 weeks later after last indicated dose of PCV13	Administer 1 dose of PPSV23 after 5 years
Children aged 24-71 months who received any incomplete schedule of 3 doses of PCV7 before age 24 months	Administer 1 dose of PCV13 now	Administer 1 dose of PPSV23 ≥8 weeks later	Administer 1 dose of PPSV23 5 year after
Completed all recommended doses of PCV13	Administer 1 dose of PPSV23 at age ≥2 years and ≥8 weeks after last indicated dose of PCV13	Administer 1 dose of PPSV23 after 5 years	
Children aged 6-18 years who have not received PCV13	Administer 1 dose of PCV13 now		
Age 19-64 years			
Never vaccinated with PCV13 or PPSV23	Administer 1 dose of PCV13 now	Administer 1 dose of PPSV23 ≥8 weeks later	Administer 1 dose of PPSV23 ≥5 years later
Previously vaccinated with 1 dose PPSV23 ≥1 year ago; never vaccinated with PCV13	Administer 1 dose of PCV13 now	Administer 1 dose of PPSV23 ≥8 weeks after PCV13, which must be ≥5 years after first dose of PPSV23	
Previously vaccinated with 2 doses of PPSV23 (last dose was ≥1 year ago); never vaccinated with PCV13	Administer 1 dose of PCV13 now		
Previously vaccinated with ≥1 dose PCV13 (≥8 weeks ago); never vaccinated with PPSV23	Administer 1 dose of PCV13 now	Administer 1 dose of PPSV23 ≥5 years later	
Previously vaccinated with ≥1 dose PCV13 (≥8 weeks ago) and 1 dose PPSV23	Administer 1 dose of PPSV23 ≥5 years after first PPSV23 dose		
Age 65 years and over			
Never vaccinated with PCV13 Previously vaccinated with ≥1 dose PCV13 (≥8 weeks ago)	Administer 1 dose of PCV13 now Administer 1 dose of PPSV23 now	Administer 1 dose of PPSV23 ≥8 weeks after PCV13, which must be ≥5 years after last dose of PPSV23	

Guidelines for Transplant patients

Kidney transplant recipients should recieveage-appropriate inactivated vaccinations as recommended for general population.[3]

Immunisation could be undertaken 3-6 months after kidney transplantation, once maintenance immunosuppressive levels are reached.[4]

For immunocompromised adults

Vaccination with both 23 valent polysaccharide vaccine (PPSV23) and 13 valent conjugate vaccine (PCV13) are safe in kidney transplant recipients.

The schedule of immunization with the vaccines is as per the recommended schedule for general adults. The ACIP guidelines suggest the following comprehensive approach for optimal vaccine efficacy among immunocompromised adults:

- If a patient receives the first dose of PCV13, it should be followed by PPSV23 at about 8 weeks later
- If patient had received PPSV23 in the past, a PCV13 dose should be administered after at least a year only
- If a patient who has received PPSV23 requires further doses of PPSV23, it should be administered at least 5 years after the last dose of PPSV23.

For immunocompromised children

Between 2 and 5 years age:

- Two doses of PCV13 administered 8 weeks apart, followed by the additional dose of PPSV23 should be administered at least 8 weeks after the last dose of PCV13

6–18 years age:

- The first dose of PCV13 should be followed by 8 weeks later a dose of PPSV23
- If patient had been administered PPSV23, PCV13 should be administered after 8 weeks later.

Vaccination of healthcare workers & household contacts:[6]

- Vaccines against Hepatitis B, pneumococcal disease, and especially Influenza should be offered to household contacts of transplant recipients.

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Pneumococcal polysaccharide Conjugate Vaccine (Adsorbed) Ph. Eur., 13-valent

For protection against pneumococcal disease in adults aged 50 years and older

Adults with chronic kidney disease are

up to **7**X** more likely to develop IPD than healthy subjects[7]

Adults with chronic kidney disease are

up to **3X** more likely to develop pneumonia than healthy subjects[8]

Adults undergoing dialysis are

up to **5X** more likely to develop pneumonia than healthy subjects[8]

REFERENCES:
1. Indian Journal of Nephrology, Supplement 1-2016, Volume 26, Chapter 5, S16. 2. Indian Journal of Nephrology, Supplement 1-2016, Volume 26, Chapter 5, S17. 3. Indian Journal of Nephrology, Supplement 1-2016, Volume 26, Chapter 6, S19. 4. Indian Journal of Nephrology, Supplement 1-2016, Volume 26, Chapter 6, S19. 5. Indian Journal of Nephrology, Supplement 1-2016, Volume 26, Chapter 6, S20. 6. Indian Journal of Nephrology, Supplement 1-2016, Volume 26, Chapter 6, S19. 7. Van Hoek AJ et al. The effect of underlying clinical conditions on the risk of developing invasive pneumococcal disease in England, J Infection 2012, 65:17-24. 8. Nagvi SB, Collins AJ. Infectious Complications in Chronic Kidney Disease,. Advances in Chronic Kidney Disease, 2006; 13(31)1 99-204.

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SUMMARY OF PRESCRIBING INFORMATION:
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Full prescribing Information available on request
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ACCORDING TO THE WORLD HEALTH ORGANIZATION, PNEUMOCOCCAL DISEASE IS A LEADING CAUSE OF VACCINE-PREVENTABLE DEATH WORLDWIDE[1]

1 WHAT IS PNEUMOCOCCAL DISEASE?

Pneumococcal disease is an infection caused by pneumococcal bacteria that can invade[2]

Important facts about Pneumococcal Disease

Pneumococcal Disease spreads easily from person to person through physical contact, coughing or sneezing[2]

Pneumococcal Disease symptoms may include shaking chills, chest pain, cough with mucus, shortness of breath, rapid breathing and poor oxygenation[2]

Pneumococcal disease is a serious infection that often results in hospitalization and even death.[1,3]

2 WHY IS VACCINATION TO PREVENT PNEUMOCOCCAL DISEASE IMPORTANT FOR ADULTS ?

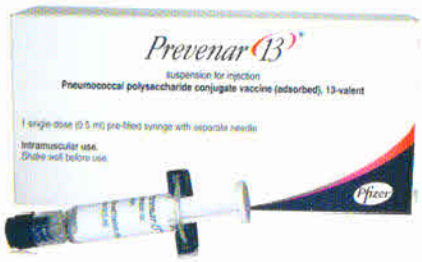
If you suffer from any of the following Chronic Diseases, you are at increased risk of Pneumococcal Disease (as compared to someone who doesn't have the disease):

Chronic Obstructive Pulmonary Disease	3.5 times[4]
Chronic Kidney Disease	3 times[5]
Undergoing Dialysis	5 times[5]
Chronic Diabetes	3.2 times[4]
Cardiovascular Disease	3 times[6]

Prevenar 13®

Pneumococcal polysaccharide Conjugate Vaccine (Adsorbed) Ph. Eur., 13-valent

1 Single Dose



GET VACCINATED STAY PROTECTED

References:

Balancing Risk Information:

Summary of Prescribing Information:

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PP-PNA-IND-0063, 25th July 2017

Are you at Risk of Pneumococcal disease

See inside to learn more about pneumococcal disease and why getting vaccinated is important.