World Health Organization	REGULATION AND PREQUALIFICATION DEPARTMENT
	VACCINE PREQUALIFICATION TEAM

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

PNEUBEVAX 14®

Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)

Biological E. Limited, India

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What is PNEUBEVAX 14® - Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)?

PNEUBEVAX 14®-Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) is a liquid vaccine for intramuscular injection, and it is indicated for active immunization against invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in children from 6 weeks of age.

The vaccine consists of pneumococcal polysaccharide conjugate bulks of 14 serotypes as drug substances produced from *Streptococcus pneumoniae* Serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F. Each of the Pneumococcal Polysaccharides are conjugated to CRM_{197} which is used as a carrier protein.

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The final formulation contains *Streptococcus pneumoniae* serotypes (each) 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F conjugated with CRM197 (20–50 µg). The antigens are adsorbed onto aluminum phosphate as an adjuvant.

PNEUBEVAX 14®-Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) is a suspension for intramuscular injection in a single and multi-dose vial. The vaccine is a whitish suspension in which the mineral carriers tend to settle down slowly.

One dose (0.5mL) of PNEUBEVAX 14® contains:

Components	Quantity
Active ingredients:	
Pneumococcal polysaccharide serotype 1	3.0 µg
Pneumococcal polysaccharide serotypes 3, 4, 5, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F (each)	2.2 µg
Pneumococcal polysaccharide serotype 6B	4.4 µg
(Polysaccharides conjugated to 20-50 µg of CRM_{197})	
Excipients:	
Adsorbed onto Aluminum Phosphate, as Al^{+++}	≤ 0.75 mg
2- Phenoxyethanol (Multidose only)	4 mg

PNEUBEVAX 14® is filled in USP type I glass vials stoppered with bromobutyl rubber stoppers and sealed using aluminium flip-off seals.

The drug substances are manufactured at M/s Biological E. Limited, Shameerpet site, India. This site is responsible for manufacturing, testing (release and stability), and storage and distribution of \Pneumococcal Monovalent Conjugate Bulks (Drug Substances).

The drug product is manufactured at M/s Biological E. Limited, Shameerpet and SEZ sites, India. The sites are responsible for manufacturing, formulation, filling, testing, packaging and distribution of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (Drug Product).

What is PNEUBEVAX 14® used for?

PNEUBEVAX 14® is indicated for active immunization against invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in children from 6 weeks of age.

How is PNEUBEVAX 14® used?

The vaccine is to be administered as a three dose primary series in infants at 6-10-14 weeks or as a two dose primary series at 6weeks-14 weeks with a booster dose at 9 months of age The vaccine should be administered intramuscularly. The preferred site is anterolateral aspect of the upper thigh. The vaccine should not be injected in the gluteal area. The vaccine should not be injected intradermally, subcutaneously or intravenously, since the safety and immunogenicity of these routes have not been evaluated.

What is PNEUBEVAX 14® characteristics?

The PNEUBEVAX 14® must be stored between 2 to 8°C. Under the recommended storage conditions, the vaccine is stable for 24 months from the date of manufacture. The vaccine can be stored up to 28 days at 2 to 8°C after partial opening of multidose vial. DO NOT FREEZE. Discard if the vaccine has been frozen

Cold chain volume per dose is 14.68 cm^3/ dose in the secondary carton box of single dose (1-dose/vial) presentation and 2.94 cm^3/ dose of multidose (5-dose/vial) presentation

The vial of PNEUBEVAX 14® bears a Vaccine Vial Monitor (VVM) type 14 affixed to vial label

Who is the regulatory authority responsible for its oversight vis a vis WHO?

PNEUBEVAX 14® is manufactured and licensed in India by Biological E. Limited. The Central Drugs Laboratory, Kasauli, India performs testing of PNEUBEVAX 14® batches and issues Analysis Reports. The Central Drug Standards Control Organization (CDSCO) of India is responsible for regulatory oversight of PNEUBEVAX 14®.

How has PNEUBEVAX 14® been studied from the clinical point of view?

Clinical data provided were from five clinical trials.

- A phase 1 trial (Study code: BECT043 & CTRI/2017/06/008759), A single arm open label non-comparative Phase-I study to evaluate safety, reactogenicity and immunogenicity of single intramuscular dose of 14-valent pneumococcal polysaccharide conjugate vaccine (without preservative) of
- Biological E. Limited in 18-45 year-old healthy adults..
- A phase 2 study (Study code: BECT044 & CTRI/2017/11/010387), An open label parallel randomised Phase-II comparative study to evaluate safety, tolerability and immunogenicity of two intramuscular doses of 14-valent pneumococcal polysaccharide conjugate vaccine administered 2 months apart to 12-23 month-old healthy Indian PCV-naïve toddlers.
- A phase 3 study (Study code: BECT051 & CTRI/2020/02/023129), a single-blind, randomized, active control study to evaluate the immunogenicity safety and tolerability of BE PCV 14 administered to 6-8 week old healthy Indian infants in a 6-10-14 weeks dosing schedule.
- A second phase 3 study (Study code: BECT061 & CTRI/2021/10/037067), a single-blind, randomized, active control study to evaluate the safety and immunogenicity of BE PCV 14 (multidose formulation including 2- phenoxyethanol as preservative) administered to 6–8-week-old healthy Indian infants in a 6-10-14 weeks dosing schedule.
- A phase 3 study (Study code: BECT056 & CTRI/2022/11/047366), a single-blind, randomized, active control study to evaluate the safety and immunogenicity of BE PCV 14 (multidose formulation including 2- phenoxyethanol as preservative) administered to 6–8-week-old healthy Indian infants in a 6, 14 weeks and 9 months dosing schedule (2+1 alternative schedule).
- A prospective multicentre Phase-IV study (CTRI/2023/09/057894) to evaluate the safety of Biological E's 14-valent pneumococcal polysaccharide conjugate vaccine when administered in 6-10-14 weeks dosing schedule to 6-8 weeks old healthy Indian infants.

The Immunogenicity of PNEUBEVAX® was assessed in one toddler (BECT044) and three infant studies (BECT051, 061 and 056). PNEUBEVAX® was administered according to a two -dose schedule in toddlers' study and according to an infant immunization schedule, three doses given at 6,10 and 10 weeks of age, which conforms with WHO recommendations for the use of PCVs. Mean age of infants were approximately 7 weeks in both infant studies.
Prevenar 13® was selected as reference vaccine in this clinical development. Prevenar 13® is a vaccine licensed and used worldwide since 2009 and pre-qualified by WHO that has consistently proven efficacy and effectiveness.

Non inferiority compared to Prevenar 13 has been clearly demonstrated in an appropriately designed and powered phase 3 pivotal study BECT051. All pre-defined criteria for non-inferiority were met for all serotypes. For the 12 common serotypes proportions achieved an

ELISA IgG antibody concentrations ≥ 0.35 µg/mL one month after dose 3 ranged 76.3% (ST6B) to 99.7% (ST14) among PNEUBEVAX 14® recipients. OPA antibody responses [titer≥LLOQ (≥1:8)] were similar in both study groups for the 12 common serotype. For serotypes 22F and 33F which were unique to PNEUBEVAX 14®, non-inferiority was demonstrated compared to the lowest performing serotype in the comparator arm. Cross protection against the serotype 6A which was not present in the PNEUBEVAX 14 was also demonstrated through the serotype 6B. The co-administration data with routinely administered vaccines at 6-10-14 weeks was acceptable.

Administered in 2+1 schedule, PNEUBEVAX 14® has demonstrated comparative immune response to Prevenar 13 for common serotypes with a robust booster response, indicating successful priming and development of immunological memory. The vaccine showed acceptable safety data comparable to Prevenar 13.

The safety and reactogenicity profile of PNEUBEVAX 14® was consistently shown to be acceptable and similar to that of Prevenar 13®, a prequalified PCV which was used as active control in this clinical program. There were no differences in the frequency, severity and nature of solicited AEs within one week of vaccination between PNEUBEVAX 14® and Prevenar 13®. Reactions were predominantly mild, none was severe. Such a reactogenicity profile is in line with what can be expected following routine vaccination of infants which were given concomitantly. There was no death, nor SAEs.

Other information about evaluation of PNEUBEVAX 14®.

As part of the prequalification process for PNEUBEVAX 14®, the Common Technical Document and the responses provided by the manufacturer to observations made by WHO have been reviewed for quality, safety and efficacy by a team of WHO experts, and found to meet WHO requirements of WHO Technical Report Series **TRS No 977** Annex 3, 2009; Recommendations to assure the quality, safety and efficacy of pneumococcal conjugate vaccines.

In addition to the information submitted to the WHO by Biological E, the decision of WHO prequalification has also been based on the site inspection of the manufacturing facility and results of testing of samples.

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