SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE BIOLOGICAL PRODUCT

PNEUMINVAC

13-valent Pneumococcal Polysaccharide Conjugate Vaccine (TT/DT)

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 ml) contains:

Pneumococcal polysaccharides serotype 1 1.8 ug	Pneumococcal polysaccharides serotype 9V 2.3 ug
Pneumococcal polysaccharides serotype 3 2.1 ug	Pneumococcal polysaccharides serotype 14 1.35 ug
Pneumococcal polysaccharides serotype 4 2.1 ug	Pneumococcal polysaccharides serotype 18C 3.65 ug
Pneumococcal polysaccharides serotype 5 1.75 ug	Pneumococcal polysaccharides serotype 19A 1.6 ug
Pneumococcal polysaccharides serotype 6A 1.85 ug	Pneumococcal polysaccharides serotype 19F 1.25 ug
Pneumococcal polysaccharides serotype 6B 4.4 ug	Pneumococcal polysaccharides serotype 23F 2.35 ug
Pneumococcal polysaccharides serotype 7F 1.75 ug	

This product uses the capsular polysaccharide antigen of streptococcus pneumonia serotypes 1, 5, 6A, 9V, 19A, 19F, and 23F to covalently combine with purified tetanus toxoid to form polysaccharide protein conjugates. The capsular polysaccharide antigen of streptococcus pneumonia serotypes 3, 4, 6B, 7F, 14 and 18C are covalently combined with purified diphtheria toxoid to form polysaccharide protein conjugates, and then 13 kinds of polysaccharide protein conjugates are mixed in a certain proportion and then adsorbed with aluminum phosphate adjuvant.

Excipients with known effect

For the full list of excipients, see section 6.1.

2. PHARMACEUTICAL FORM

Suspension for Injection.

This product is a white suspension.

3. CLINICAL PARTICULARS

3.1 Therapeutic indications

This product is indicated for infants and children from 6 weeks to 5 years old (before the 6th birthday).

After being vaccinated with this product, it can stimulate the body to produce immunity and is used to prevent infectious diseases caused by 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F) of streptococcus pneumonia. This product cannot prevent infectious diseases caused by other pneumococcal serotypes and other microorganisms.

The use of the vaccine should be in accordance with official recommendations.

3.2 Posology and method of administration

The immunization schedules for PCV 13 should be based on official recommendations.

Method of administration

Shake before use and inject intramuscularly. The preferred injection site for infants is the anterolateral thigh. The preferred injection site for toddlers and children is the outer deltoid muscle of the upper arm.

Posology

Infants aged 2~6 months: 4 doses in total. It is recommended that the first dose be vaccinated at 2 months of age (at least 6 weeks of age), and 3 doses of primary series, with an interval of 2 months between each dose: 1 booster vaccination at 12 to 15 months of age,

Infants aged 7~11 months: 3 doses in total. Two doses of primary series, with an interval of at least 1 month between each dose; a booster vaccination after 12 months of age, at least 2-month interval from the second dose.

Toddlers aged 12~23 months: 2 doses at least 2-month interval.

Children aged 24 months～5 years: 1 dose.

For instructions on administration, see section 6.6

3.3 Contraindications

Hypersensitivity to any component of the product, including excipients, diphtheria toxoid or tetanus toxoid, etc.

3.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Precautions

1. Freezing is strictly forbidden.
2. Shake the vaccine container well before use. Do not use the vaccine if the container shows abnormalities, such as crack, foreign matters, clumps not dispersed on shaking, and illegible label.
3. This product is for intramuscular injection only, and intravenous injection is prohibited.

4. The vaccine shall be administered immediately after unsealing. A single human dose shall be used up each time according to prescribing information.
5. Under no circumstances shall the tetanus toxoid and diphtheria toxoid contained in the vaccine replace the routine immunization of tetanus vaccine and diphtheria vaccine.
6. The vaccination should be postponed in case of fever, acute disease, and acute attack of chronic disease.
7. Appropriate monitoring and medical care and rescue measures should be readily available in case of occurrence of rare hypersensitivity reactions during vaccination.
8. Cautions should be taken tor vaccination in recipients with thrombocytopenia, any coagulopathy or those who are receiving anticoagulant treatment.
9. This product cannot guarantee all recipients can be protected from any diseases caused by *Streptococcus pneumoniae*.
10. Given there is still no available safety and immunogenicity data for this product in immuno-compromised individuals (e.g., malignancy or nephrotic syndrome), vaccination in this special group should be considered on an individual basis.
11. The use of this product does not replace the use of 23-valent Pneumococcal Polysaccharide Vaccine in children ≥24 months of age with conditions such as sickle cell disease, asplenia, HIV infection, chronic illness, or those who are immuno-compromised.
12. Preterm infants should be monitored for the potential risk of apnea during primary series.

4.5 Interaction with other medicinal products and other forms of interaction
No concomitant immunization data are available for the product. During the phase III clinical trial of the product, the interval between vaccination of any other vaccine was ≥ 7 days. No adverse impact of was observed on the immunogenicity of this product under the indicated immunization interval.

4.6 Fertility, pregnancy and lactation
Pregnancy

There are no data from the use of pneumococcal 13-valent conjugate vaccine in pregnant women. Therefore, the use of PNEUMINVAC should be avoided during pregnancy.

Breast-feeding

It is unknown whether pneumococcal 13-valent conjugate vaccine is excreted in human milk.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

4.7 Effects on ability to drive and use machines
PCV 13 has no or negligible influence on the ability to drive and use machines. However, some of the adverse effects may temporarily affect the ability to drive or use machines.

4.8 Undesirable effects

Clinical trial

2160 subjects aged 6 weeks to 5 years participated in a clinical study of this product in China; 1240 of them received at least one dose of this product. The safety of this product system is observed from the start of vaccination to 30 days after each dose, and the long-term safety is observed to 6 months after the primary series.

(1) Summary description

Adverse reactions of this product are classified according to the following criteria recommended by the CIOMS: Very common (≥ 10%), Common (1%~10%, including 1%), Occasionally (0.1%~1%, including 0.1%), Rare (0.01%~0.1%, including 0.01%), Very rare (<0.01%).

2~6 months old:

① Systemic adverse reactions

Very common: fever, crying.

Common: cough, diarrhea, vomiting, loss of appetite, fatigue.

Occasionally: upper respiratory tract infection.

② Local adverse reactions

Very common: redness, swelling, induration.

Common: pain.

Occasionally: rash (injection site).

③ Serious adverse reactions

One case of serious adverse event (SAE) occurred during the booster immunization phase of the phase III clinical trial of this product in the 2-month-old group was febrile seizures and acute upper respiratory tract infection, which were determined to may be related to this product, and other serious adverse events were not related to this product.

7 months old～5 years old:

① Systemic adverse reactions

Very common: fever.

Common: crying, diarrhea, cough, vomiting, loss of appetite, fatigue.

Occasionally: myalgia, headache, allergic dermatitis.

② Local adverse reactions

Very common: redness.

Common: swelling, induration, pain.

Occasionally: itching, rash (injection site), skin and mucosal abnormalities.

(2) The occurrence of adverse reactions in phase III clinical trials

① The incidence and severity of soliciting adverse reactions

The phase III clinical trial of this product and the positive control vaccine (Prevnar 13®) in China for

the incidence and severity of adverse reactions after primary immunization and booster immunization are detailed in Table 1 and Table 2.

Table 1. Incidence Rates of Solicited Local Adverse Reactions in Phase III Clinical Trial in China

Symptoms and Grading of Local Adverse Reaction	2 Months		7~11 Months	12~23 Months	2~5 Years
	PCV13 (TT/DT)	Prevnar 13®	PCV13 (TT/DT)	PCV13 (TT/DT)	PCV13 (TT/DT)
	N*=517~600	N*=523~600	N*=164~200	N*=200	N*=200
	%[a]	%[a]	%[a]	%	%
Pain					
Any	5.17	3.00	0.50	2.00	4.00
Grade 1[b]	4.67	2.50	0.50	2.00	3.50
Grade 2[b]	0.50	0.67	0.00	0.00	0.50
Grade 3[b]	0.00	0.00	0.00	0.00	0.00
Redness					
Any	36.00	42.67	12.50	28.00	18.50
Grade 1[c]	21.17	21.50	4.00	12.00	8.50
Grade 2[c]	17.83	27.33	7.50	15.50	9.00
Grade 3[c]	2.17	2.50	1.00	1.00	1.00
Swelling					
Any	12.33	24.33	6.00	7.50	9.50
Grade 1[c]	6.83	10.67	1.00	4.50	5.50
Grade 2[c]	5.00	13.83	4.50	3.00	3.50
Grade 3[c]	1.50	1.72	0.50	0.00	0.50
Induration					
Any	25.17	21.50	8.50	11.50	6.50

Grade 1[c]	12.67	13.83	4.50	3.50	4.50
Grade 2[c]	13.67	8.17	4.00	8.50	2.00
Grade 3[c]	1.67	1.34	0.00	0.00	0.00
Rash (injection site)					
Any	0.33	0.76	0.00	0.00	1.50
Grade 1[c]	0.19	0.19	0.00	0.00	0.50
Grade 2[c]	0.17	0.38	0.00	0.00	1.00
Grade 3[c]	0.00	0.19	0.00	0.00	0.00
Itching					
Any	0.19	0.19	0.00	1.00	1.50
Grade 1[d]	0.19	0.19	0.00	1.00	1.00
Grade 2[d]	0.00	0.00	0.00	0.00	0.50
Grade 3[d]	0.00	0.00	0.00	0.00	0.00
Skin and mucosal abnormalities					
Any	0.00	0.00	0.00	0.00	0.50
Grade 1[e]	0.00	0.00	0.00	0.00	0.50
Grade 2[e]	0.00	0.00	0.00	0.00	0.00
Grade 3[e]	0.00	0.00	0.00	0.00	0.00
Any local reaction					
Any	43.67	49.33	13.50	30.50	22.00
Grade 1	29.67	33.67	6.50	14.00	15.00
Grade 2	24.67	32.83	7.50	19.00	10.50
Grade 3	2.83	2.67	1.00	1.00	1.00
*N=number of subjects reporting “yes” for at least 1 day, or “no” for all 30 days. The number of					

subjects for primary immunization and booster immunization is listed from small to large.

a: The minimum and maximum incidence rates for local adverse reactions after primary and booster immunization.

b: Grade 1, not affecting activities; grade 2, affecting activities or multiple use of non-narcotic analgesics; grade 3, affecting daily activities or multiple use of narcotic analgesics.

c: Grade 1, ＜15 mm; grade 2, 15~30 mm; grade 3, ＞ 30 mm.

d: Grade 1, mild itching in injecting site; grade 2, moderate itching in limbs with vaccination; grade 3, systemic itching.

e: Grade 1, redness, itching; grade 2, diffuse, maculopapular rash, dry, desquamation; grade 3, blisters, dampness, desquamation or ulcers.

Table 2. Incidence Rates of Solicited Systemic Adverse Reactions in Phase III Clinical Trial in China

Symptoms and Grading of Systemic Adverse Reaction	2 Months		7~11 Months	12~23 Months	2~5 Years
	PCV13 (TT/DT)	Prevnar 13®	PCV13 (TT/DT)	PCV13 (TT/DT)	PCV13 (TT/DT)
	N*=517~600	N*=523~600	N*=164~200	N*=200	N*=200
	%[a]	%[a]	%[a]	%	%
Fever					
Any	52.83	59.50	59.00	43.50	25.00
Grade 1[b]	44.17	47.00	44.50	27.00	14.50
Grade 2[b]	17.17	26.00	24.50	20.50	9.50
Grade 3[b]	0.50	1.53	1.00	1.50	1.00
Darrhea					
Any	7.50	8.33	4.50	4.00	0.00
Grade 1[c]	5.00	6.67	4.50	3.00	0.00
Grade 2[c]	2.83	1.83	0.61	1.00	0.00
Grade 3[c]	0.17	0.17	0.00	0.00	0.00
Crying					
Any	14.33	16.50	8.50	5.00	-

Grade 1[d]	11.50	14.00	7.00	3.50	-
Grade 2[d]	4.17	3.50	1.50	1.50	-
Grade 3[d]	0.00	0.00~0.17	0.00	0.00	-
Loss of appetite					
Any	3.33	3.83	2.00	2.00	-
Grade 1[e]	2.67	3.67	2.00	1.50	-
Grade 2[e]	0.67	0.17	0.00	0.50	-
Grade 3[e]	0.00	0.00	0.00	0.00	-
Fatigue					
Any	3.83	3.33	1.50	0.50	1.00
Grade 1[f]	3.67	3.17	1.50	0.50	0.50
Grade 2[f]	3.33	0.19	0.00	0.00	0.50
Grade 3[f]	0.00	0.00	0.00	0.00	0.00
Vomiting					
Any	3.17	5.33	1.50	3.00	-
Grade 1[g]	2.67	4.83	1.50	2.00	-
Grade 2[g]	0.67	0.67	0.00	1.00	-
Grade 3[g]	0.00	0.00	0.00	0.00	-
Cough					
Any	9.67	9.67	2.50	2.00	1.50
Grade 1[h]	7.00	6.67	2.00	1.50	1.00
Grade 2[h]	3.00	3.67	0.61	0.50	0.50
Grade 3[h]	0.00	0.00	0.00	0.00	0.00
Myalgia					

Any	-	-	-	-	1.50
Grade 1[i]	-	-	-	-	1.00
Grade 2[i]	-	-	-	-	0.50
Grade 3[i]	-	-	-	-	0.00
Headache					
Any	-	-	-	-	0.50
Grade 1[j]	-	-	-	-	0.50
Grade 1[j]	-	-	-	-	0.00
Grade 1[j]	-	-	-	-	0.00
Any systemic reaction					
Any	59.50	64.67	63.50	47.50	25.50
Grade 1	52.17	56.33	51.50	33.00	15.50
Grade 2	23.67	30.00	25.00	22.00	10.50
Grade 3	0.67	1.53	1.00	1.50	1.00

*N=number of subjects reporting “yes” for at least 1 day, or “no” for all 30 days. The number of subjects for primary immunization and booster immunization is listed from small to large.

a: The minimum and maximum incidence rates for local adverse reactions after primary and booster immunization.

b: Grade 1, 37.1~37.5℃; grade 2, 37.6~39.0℃; grade 3, ＞ 39.0℃.

c: Grade 1, mild or transient with 2-3 times of loose stools/day, or mild diarrhea lasting < 1 week; grade 2, moderate or persistent diarrhea, 4-5 times/day, or diarrhea lasting > 1 week; grade 3, > 6 times of watery stool/day, or bloody diarrhea, orthostatic hypotension, electrolyte imbalance, in need of intravenous infusion of > 2 L.

d: Grade 1, slight increase in frequency than usual; grade 2, doubled frequency than usual; grade 3, doubled frequency than usual, and lasts > 3 days.

e: Grade1, the frequency or amount of food eaten is slightly reduced than usual; grade 2, the frequency or amount of food eaten is reduced by one time than usual; grade 3, the frequency or amount of food eaten is reduced by more than double than usual, and lasts for more than 1 day.

f: Grade 1, slight reduction in normal activities for < 48 h; grade 2, 20%-50% reduction in normal activities for > 48 h; grade 3, > 50% or > 72 h reduction in normal activities.

g: Grade 1, once/24 h, with basically normal intake and will not affect activities; grade 2, 2-3 times/24 h, with significantly reduced intake or restricted activities; grade 3, 4~6 times/24 h, with no significant intake, and in need of intravenous infusion.

h: Grade 1, transient, no treatment required; grade 2, persistent and controllable cough; grade 3, uncontrollable paroxysmal cough.

i: Grade 1, not affecting daily activities; grade 2, tender muscles in non-vaccination sites, affecting daily activities mildly; grade 3, severe tender muscles, affecting daily activities severely.

j: Grade1, not affecting activities, no treatment is required; grade 2, transient, slightly affecting activities and requires treatment; grade 3, severely affecting daily activities, and responds to initial anesthetic treatment.

② The incidence rate and severity of unsolicited adverse reactions

The unsolicited adverse reactions collected in the phase III clinical trial of this product included 1 case of upper respiratory tract infection (incidence rate of 0.19%) in the 2~6 month-old group and 1 case of allergic dermatitis (incidence rate of 0.50%) in the 7-month~5-year-old group. The severity is all level 2.

4.9 Overdose

Overdose with PNEUMINVAC is unlikely due to its presentation as a pre-filled syringe.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: vaccines, pneumococcal vaccines; ATC code: J07AL02

This product uses the capsular polysaccharide antigen of streptococcus pneumonia serotypes 1, 5, 6A, 9V, 19A, 19F, and 23F to covalently combine with purified tetanus toxoid to form polysaccharide protein conjugates. The capsular polysaccharide antigen of streptococcus pneumonia serotypes 3, 4, 6B, 7F, 14 and 18C are covalently combined with purified diphtheria toxoid to form polysaccharide protein conjugate.

Clinical trial

In China, the pivotal phase III clinical trial of this product in China enrolled 2100 healthy children between 2 months and 5 years of age to evaluate the safety and immunogenicity of the product vaccinated with this product. Among them, 1200 subjects at the age of 2 months (at least 6 weeks of age) adopt a randomized, double-blind, positive control non-inferiority trial design. The subjects are randomly vaccinated with this product or the control vaccine at a ratio of 1:1 (Prevnar 13®), the vaccination schedule is 1 dose each for 2, 4, 6 months old and 12-15 months old; 300 subjects each for 7-11 months age, 12-23 months age, 2-5 years age group, randomized, partially double-blind , negative control design, subjects are randomly vaccinated with this product or the control vaccine (Haemophilus influenzae type b conjugate vaccine, Hib) at a ratio of 2:1, and the vaccination schedule for 7 to 11 months age group are 0, 1 month and 12 to 15 months of age (the interval between the third dose and the second dose is at least 2 months) vaccinated 1 dose each, the vaccination schedule for 12 to 23 months age group is 0 and 2 months each, and 2 to 5 years age group vaccinated only 1 dose.

The immunogenicity endpoints included the percentage of subjects with lgG antibody concentration was ≥0.35 ug/mL (positive rate) and the geometric mean concentration(GMC) of serotype-specific lgG antibody one month post the final dose of primary series and booster dose,

as well as the percentage of subjects with vaccine serotype-specific OPA titer was ≥ 1:8 (positive rate) and OPA geometric mean titer(GMT) one month post the final dose of primary series and booster dose. Enzyme-linked immunosorbent assay (ELISA) was utilized to detect the IgG antibody concentration in all serum samples collected from each group; additionally, a subset of sera randomly obtained from 100 subjects in 2 months age test and control group, 100 subjects in 7~11 months age test group, 12~23 months age test group and 2~5 years age test group respectively, and 50 subjects in 7~11 months age test group, 12~23 months age test group and 2~5 years age control group respectively were tested by opsonophagocytic assay (OPA) to measure the ability of serotype-specific functional antibodies to eliminate corresponding pneumococci by promoting complement-mediated phagocytosis.

The non-inferiority can be established for the 2-month-old group through demonstrating the lower limit of two-sided 97.5% CI for the difference IgG positive rate (test group-control group) were greater than -10%, and the lower limit of double-sided 97.5% CI for IgG GMC ratio between groups (test group/control group) was greater than 0.5. The results of the study showed that no matter the primary series (3 doses) or booster (the 4th dose), all 13 serotype IgG positive rate and GMC of the test group were not inferior to the control group. OPA antibody results showed that all 13 serotypes in the test group could induce a functional OPA antibody response. The immunogenicity data is shown in Table 3 to Table 6.

The immunogenicity data of 7 months to 5 years of age is shown in Table 7 to Table 10.

Table 3 Proportion of Subjects with IgG Antibody Concentration≥0.35ug/mL in Subjects Aged 2 Months (Positive rate) (PPS)

Serotypes	Post primary immunization			Post booster immunization		
	PCV13 (TT/DT) % (95%CI) N=528	Prevnar 13® %(95%CI) N=531	PCV13 (TT/DT)-Prevnar 13® %(97.5%CI)	PCV13 (TT/DT) % (95%CI) N=463	Prevnar 13® %(95%CI) N=455	PCV13 (TT/DT)-Prevnar 13® %(97.5%CI)
1	100.0 (99.30~100.0)	99.81 (98.96~100.0)	0.19 (-0.23,0.61)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)
3	100.0 (99.30~100.0)	93.41 (90.95~95.37)	6.59 (4.18,9.00)	100.0 (99.21~100.0)	99.56 (98.42~99.95)	0.44 (-0.26,1.13)
4	100.0 (99.30~100.0)	99.44 (98.36~99.88)	0.56 (-0.16,1.29)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)
5	100.0 (99.30~100.0)	99.25 (98.08~99.79)	0.75 (-0.09,1.59)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)

6A	99.05 (97.80~99.69)	99.62 (98.65~99.95)	-0.57 (-1.69,0.55)	100.0 (99.21~100.0)	99.78 (98.78~99.99)	0.22 (-0.27,0.71)
6B	99.43 (98.35~99.88)	99.25 (98.08~99.79)	0.19 (-0.93,1.30)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)
7F	99.81 (98.95~100.0)	99.81 (98.96~100.0)	-0.00 (-0.60,0.60)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)
9V	99.81 (98.95~100.0)	99.81 (98.96~100.0)	-0.00 (-0.60,0.60)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)
14	100.0 (99.30~100.0)	100.0 (99.31~100.0)	0.00 (-0.82,0.83)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)
18C	98.96 (97.54~99.58)	99.25 (98.08~99.79)	-0.38 (-1.72,0.95)	100.0 (99.21~100.0)	99.78 (98.78~99.99)	0.22 (-0.27,0.71)
19A	100.0 (99.30~100.0)	100.0 (99.31~100.0)	0.00 (-0.82,0.83)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)
19F	100.0 (99.30~100.0)	100.0 (99.31~100.0)	0.00 (-0.82,0.83)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)
23F	99.81 (98.95~100.0)	99.81 (98.96~100.0)	-0.00 (-0.60,0.60)	100.0 (99.21~100.0)	100.0 (99.19~100.0)	0.00 (-0.94,0.96)

Table 4 IgG Antibody GMC in Subjects Aged 2 Months (PPS)

Serotypes	Post primary immunization			Post booster immunization		
	PCV13 (TT/DT) GMC (95%CI)	Prevnar 13® GMC(95%CI)	PCV13 (TT/DT)/ Prevnar 13®	PCV13 (TT/DT) GMC (95%CI)	Prevnar 13® GMC(95%CI)	PCV13 (TT/DT)/ Prevnar 13®

	N=528	N=531	%(97.5%CI)	N=463	N=455	%(97.5%CI)
1	5.90 (5.53~6.31)	4.28 (4.02~4.56)	1.38 (1.23,1.55)	8.15 (7.64~8.68)	6.99 (6.50~7.53)	1.17 (1.05,1.29)
3	2.06 (1.96~2.16)	0.85 (0.80~0.89)	2.45 (2.24,2.63)	2.96 (2.79~3.14)	1.78 (1.66~1.90)	1.66 (1.51,1.86)
4	4.88 (4.54~5.24)	2.25 (2.12~2.39)	2.19 (1.95,2.40)	6.40 (5.94~6.89)	3.95 (3.65~4.27)	1.62 (1.45,1.82)
5	2.79 (2.63~2.96)	2.00 (1.89~2.12)	1.38 (1.26,1.51)	4.18 (3.95~4.43)	3.18 (2.97~3.40)	1.32 (1.17,1.45)
6A	4.35 (4.02~4.70)	3.74 (3.49~4.00)	1.17 (1.02,1.32)	8.45 (7.83~9.13)	6.89 (6.38~7.44)	1.23 (1.07,1.38)
6B	5.09 (4.68~5.54)	4.04 (3.75~4.35)	1.26 (1.10,1.45)	13.41 (12.43~14.47)	10.93 (10.05~11.89)	1.23 (1.07,1.41)
7F	5.60 (5.27~5.95)	6.54 (6.11~7.00)	0.85 (0.78,0.95)	8.06 (7.61~8.53)	7.19 (6.72~7.69)	1.12 (1.02,1.23)
9V	5.90 (5.49~6.34)	3.15 (2.95~3.36)	1.86 (1.70,2.09)	10.42 (9.72~11.17)	5.68 (5.27~6.11)	1.82 (1.62,2.04)
14	21.72 (19.86~23.76)	18.06 (16.71~19.52)	1.20 (1.05,1.38)	34.21 (32.25~36.28)	20.43 (19.14~21.82)	1.66 (1.51,1.86)
18C	4.54 (4.17~4.94)	3.65 (3.38~3.94)	1.23 (1.10,1.41)	5.97 (5.61~6.36)	5.13 (4.75~5.55)	1.17 (1.05,1.32)
19A	6.33	4.98	1.26	18.74	12.95	1.45

	(5.92~6.78)	(4.67~5.30)	(1.15,1.41)	(17.52~20.05)	(12.04~13.94)	(1.29,1.62)
19F	10.95 (10.23~11.71)	5.43 (5.12~5.77)	2.00 (1.82,2.24)	19.77 (18.55~21.07)	9.95 (9.28~10.67)	2.00 (1.78,2.19)
23F	7.38 (6.77~8.03)	4.49 (4.13~4.87)	1.66 (1.45,1.86)	10.54 (9.83~11.31)	11.12 (10.25~12.06)	0.95 (0.83,1.07)

Table 5 Proportion of Subjects with OPA Antibody Titer ≥1:8 in Subjects Aged 2 Months (Positive rate) (PPS)

Serotypes	Post primary immunization		Post booster immunization	
	PCV13 (TT/DT) %(95%CI) N=103	Prevnar 13® %(95%CI) N=100	PCV13 (TT/DT) %(95%CI) N=102	Prevnar 13® %(95%CI) N=108
1	99.03 (94.71~99.98)	99.00 (94.55~99.97)	100.0 (96.45~100.0)	100.0 (96.64~100.0)
3	100.0 (96.48~100.0)	100.0 (96.38~100.0)	100.0 (96.45~100.0)	100.0 (96.64~100.0)
4	100.0 (96.48~100.0)	100.0 (96.38~100.0)	100.0 (96.45~100.0)	100.0 (96.64~100.0)
5	100.0 (96.48~100.0)	100.0 (96.38~100.0)	100.0 (96.45~100.0)	100.0 (96.64~100.0)
6A	97.09 (91.72~99.40)	100.0 (96.38~100.0)	100.0 (94.66~100.0)	100.0 (96.64~100.0)
6B	100.0 (96.48~100.0)	99.00 (94.55~99.97)	100.0 (96.45~100.0)	96.30 (90.79~98.98)
7F	100.0 (96.48~100.0)	100.0 (96.38~100.0)	100.0 (96.45~100.0)	100.0 (96.64~100.0)
9V	100.0 (96.48~100.0)	99.00 (94.55~99.97)	100.0 (96.45~100.0)	100.0 (96.64~100.0)

14	99.03 (94.71~99.98)	100.0 (96.38~100.0)	100.0 (96.45~100.0)	100.0 (96.64~100.0)
18C	99.03 (94.71~99.98)	99.00 (94.55~99.97)	100.0 (96.45~100.0)	100.0 (96.64~100.0)
19A	99.03 (94.71~99.98)	100.0 (96.38~100.0)	100.0 (96.45~100.0)	100.0 (96.64~100.0)
19F	99.03 (94.71~99.98)	99.00 (94.55~99.97)	100.0 (96.45~100.0)	97.22 (92.10~99.42)
23F	98.06 (93.16~99.76)	96.00 (90.07~98.90)	99.02 (94.66~100.0)	97.22 (92.10~99.42)

Table 6 OPA Antibody GMT in Subjects Aged 2 Months (PPS)

Serotypes	Post primary immunization		Post booster immunization	
	PCV13 (TT/DT) GMT(95%CI) N=103	Prevnar 13® GMT(95%CI) N=100	PCV13 (TT/DT) GMT(95%CI) N=102	Prevnar 13® GMT(95%CI) N=108
1	280.72 (212.25~371.27)	161.21 (120.92~214.92)	949.18 (728.3~1237.1)	826.27 (623.3~1095.3)
3	1092.35 (871.4~1369.3)	346.35 (287.90~416.67)	3311.52 (2597.7~4251.0)	1098.42 (870.4~1386.1)
4	2169.46 (1730.9~2719.2)	1418.05 (1140.1~1763.8)	16010.58 (12425~20631)	12582.24 (9939~15928)
5	2116.13 (1695.7~2640.8)	979.38 (782.8~1209.8)	5737.53 (4413.9~7458.2)	2540.43 (2035.1~3171.3)
6A	1694.29 (1241.9~2311.4)	3280.02 (2623.9~4100.2)	9599.28 (7095~12987)	26721.47 (22196~32209)
6B	1906.53 (1494.7~2431.9)	2929.89 (2205.9~3891.5)	8462.55 (6650~10769)	17541.05 (11563~26611)

7F	3788.30 (2941.6~4878.7)	10745.32 (8554~13498)	10353.07 (8459~12671)	12801.94 (10220~16036)
9V	1557.80 (1206.7~2011.0)	1441.77 (1099.3~1890.9)	21443.72 (16991~27063)	13478.22 (10619~17107)
14	4196..17 (3006.4~5856.8)	4999.17 (3836.0~6515.0)	20635.19 (16279~26157)	10796.17 (8456~13785)
18C	1159.07 (891.0~1507.8)	1497.58 (1152.9~1945.4)	4858.02 (3832.7~6157.6)	7263.57 (5737.0~9196.3)
19A	837.26 (649.5~1079.3)	1173.81 (945.3~1457.5)	9685.10 (7809~12011)	8693.65 (6836~11056)
19F	937.06 (726.7~1208.4)	708.87 (555.61~904.40)	5082.31 (3920.7~6588.0)	4130.48 (2981.3~5722.6)
23F	2195.35 (1617.6~2968.6)	3824.53 (2547.6~5741.6)	7099.70 (5398.1~9337.6)	30556.60 (21003~44456)

Table 7 Proportion of Subjects with IgG Antibody Concentration≥0.35ug/mL in Subjects Aged 7 Months to 5 Years (Positive rate) (PPS)

Serotypes	Post primary immunization			Post booster immunization
	7~11 months	12~23 months	2~5 years	7~11 months
	PCV13 (TT/DT) %(95%CI) N=176	PCV13 (TT/DT) %(95%CI) N=150	PCV13 (TT/DT) %(95%CI) N=191	PCV13 (TT/DT) %(95%CI) N=141
1	100.0 (97.93~100.0)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
3	100.0 (97.93~100.0)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
4	100.0 (97.93~100.0)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)

5	100.0 (97.93~100.0)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
6A	98.86 (95.96~99.86)	100.0 (97.57~100.0)	99.48 (97.12~99.99)	100.0 (97.42~100.0)
6B	98.30 (95.10~99.65)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
7F	100.0 (97.93~100.0)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
9V	100.0 (97.93~100.0)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
14	100.0 (97.93~100.0)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
18C	98.86 (95.96~99.86)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
19A	100.0 (97.93~100.0)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
19F	100.0 (97.93~100.0)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)
23F	98.86 (95.96~99.86)	100.0 (97.57~100.0)	100.0 (98.09~100.0)	100.0 (97.42~100.0)

Table 8 IgG Antibody GMC in Subjects Aged 7 Months to 5 Years (PPS)

Serotypes	Post primary immunization			Post booster immunization
	7~11 months	12~23 months	2~5 years	7~11 months
	PCV13 (TT/DT) GMC(95%CI) N=176	PCV13 (TT/DT) GMC(95%CI) N=150	PCV13 (TT/DT) GMC(95%CI) N=191	PCV13 (TT/DT) GMC(95%CI) N=141

1	3.12 (2.85~3.42)	3.20 (3.01~3.41)	2.41 (2.26~2.57)	4.41 (4.07~4.78)
3	2.74 (2.50~3.00)	1.55 (1.45~1.65)	1.19 (1.10~1.27)	2.19 (2.04~2.36)
4	6.13 (5.61~6.70)	4.78 (4.40~5.20)	4.13 (3.74~4.56)	4.17 (3.83~4.55)
5	4.04 (3.68~4.43)	3.74 (3.49~4.02)	4.03 (3.74~4.35)	3.56 (3.35~3.78)
6A	0.99 (0.90~1.09)	1.82 (1.65~2.02)	1.88 (1.68~2.10)	2.93 (2.63~3.26)
6B	1.33 (1.18~1.50)	3.51 (3.16~3.88)	4.52 (3.93~5.20)	5.63 (5.14~6.17)
7F	6.22 (5.60~6.92)	6.01 (5.55~6.51)	5.00 (4.56~5.48)	6.17 (5.73~6.65)
9V	3.93 (3.48~4.44)	4.53 (4.09~5.02)	3.63 (3.23~4.09)	4.58 (4.19~5.01)
14	9.91 (8.87~11.07)	14.96 (13.55~16.51)	12.61 (11.04~14.40)	22.14 (20.51~23.89)
18C	5.95 (5.22~6.77)	6.12 (5.61~6.67)	6.64 (5.97~7.38)	4.59 (4.22~5.00)
19A	5.19 (4.71~5.71)	7.04 (6.45~7.68)	7.40 (6.68~8.21)	8.49 (7.80~9.24)
19F	8.09 (7.26~9.01)	8.09 (7.41~8.82)	8.03 (7.15~9.02)	9.97 (9.20~10.80)
23F	2.34 (2.04~2.69)	3.64 (3.30~4.01)	3.79 (3.32~4.31)	4.81 (4.33~5.35)

Table 9 Proportion of Subjects with OPA Antibody Titer ≥1:8 in Subjects Aged 7 Months to 5 Years (Positive rate) (PPS)

Serotypes	Post primary immunization			Post booster immunization
	7~11 months	12~23 months	2~5 years	7~11 months
	PCV13 (TT/DT) %(95%CI) N=106	PCV13 (TT/DT) %(95%CI) N=103	PCV13 (TT/DT) %(95%CI) N=108	PCV13 (TT/DT) %(95%CI) N=109
1	94.34 (88.09~97.89)	100.0 (96.48~100.0)	92.59 (85.93~96.75)	94.50 (88.40~97.95)
3	100.0 (96.58~100.0)	100.0 (96.48~100.0)	100.0 (98.09~100.0)	100.0 (96.67~100.0)

4	99.06 (94.86~99.98)	100.0 (96.48~100.0)	100.0 (96.64~100.0)	100.0 (96.67~100.0)
5	100.0 (96.58~100.0)	100.0 (96.48~100.0)	100.0 (96.64~100.0)	100.0 (96.67~100.0)
6A	72.64 (63.13~80.85)	97.09 (91.72~99.40)	100.0 (96.64~100.0)	95.41 (89.62~98.49)
6B	80.19 (71.32~87.30)	100.0 (96.48~100.0)	99.07 (94.95~99.98)	97.25 (92.17~99.43)
7F	100.0 (96.58~100.0)	100.0 (96.48~100.0)	100.0 (96.64~100.0)	100.0 (96.67~100.0)
9V	99.06 (94.86~99.98)	100.0 (96.48~100.0)	100.0 (96.64~100.0)	100.0 (96.67~100.0)
14	100.0 (96.58~100.0)	100.0 (96.48~100.0)	100.0 (96.64~100.0)	100.0 (96.67~100.0)
18C	99.06 (94.86~99.98)	100.0 (96.48~100.0)	100.0 (96.64~100.0)	100.0 (96.67~100.0)
19A	99.06 (94.86~99.98)	100.0 (96.48~100.0)	100.0 (96.64~100.0)	100.0 (96.67~100.0)
19F	98.11 (93.35~99.77)	100.0 (96.48~100.0)	100.0 (96.64~100.0)	99.08 (94.99~99.98)
23F	90..57 (83.33~95.38)	97.09 (91.72~99.40)	100.0 (96.64~100.0)	97.25 (92.17~99.43)

Table 10 OPA Antibody GMT in Subjects Aged 7 Months to 5 Years (PPS)

Serotypes	Post primary immunization			Post booster immunization
	7~11 months	12~23 months	2~5 years	7~11 months
	PCV13 (TT/DT)	PCV13 (TT/DT)	PCV13 (TT/DT)	PCV13 (TT/DT)

	GMT(95%CI) N=106	GMT(95%CI) N=103	GMT(95%CI) N=108	GMT(95%CI) N=109
1	58.09 (45.55~74.07)	89.35 (74.69~106.89)	33.18 (26.47~41.59)	208.28 (153.04~283.46)
3	1082.87 (925.6~1266.8)	777.35 (670.97~900.60)	526.85 (434.63~638.63)	1165.49 (976.8~1390.6)
4	1325.38 (1082.2~1623.2)	4553.20 (3927.9~5278.0)	5852.97 (4799.6~7137.5)	3349.95 (2551.6~4398.1)
5	481.93 (407.16~570.44)	836.56 (705.28~992.28)	486.12 (395.60~597.35)	1135.30 (880.8~1463.4)
6A	115.43 (68.24~195.26)	1933.64 (1391.5~2687.1)	5254.69 (4236.9~6517.0)	1846.15 (1286.1~2650.0)
6B	234.59 (140.61~391.40)	4471.38 (3476.2~5751.5)	5865.41 (4493.2~7656.7)	1504.98 (1117.5~2026.8)
7F	6184.02 (5132.7~7450.7)	9960.93 (8352~11880)	12446.38 (10736~14429)	8424.30 (7169.5~9898.7)
9V	910.19 (713.1~1161.8)	4134.21 (3356.9~5091.6)	5483.61 (4452.1~6754.1)	7570.27 (6001.9~9548.4)
14	3875.09 (3095.8~4850.6)	18502.16 (15667~21851)	10550.61 (8656~12860)	6693.36 (5272.0~8497.9)
18C	1145.63 (916.9~1431.4)	4363.29 (3692.1~5156.5)	4642.68 (3868.5~5571.8)	1129.65 (927.8~1375.4)
19A	1135.59 (930.9~1385.3)	3540.43 (2948.0~4252.0)	3856.29 (3244.8~4583.0)	2353.21 (1975.1~2803.7)
19F	931.33 (734.4~1181.1)	2540.35 (2178.4~2962.4)	2597.63 (2211.9~3050.6)	1171.18 (940.7~1458.2)
23F	423.86 (280.98~639.41)	3661.54 (2595.5~5165.5)	5529.44 (4340.6~7043.9)	1202.77 (877.9~1647.8)

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of single dose toxicity, repeat dose toxicity, stimulating test and systemic active anaphylaxis test.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients: Sodium oxide, succinic acid, polysorbate 80, aluminum phosphate.

6.2 Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

6.3 Shelf life

The shelf life of the vaccine is 24 months.

6.4 Special precautions for storage

Store and ship at 2-8°C, protect from light. Do not freeze.

6.5 Nature and contents of container

0.5 ml suspension for injection in pre-filled syringe (Type I glass) with a plunger stopper (latex-free chlorobutyl rubber) and protective-tip cap (latex-free isoprene bromobutyl rubber).

Box, 1 syringe @ 0.5 mL

6.6 Special precautions for disposal and other handling

During storage, a white deposit and clear supernatant can be observed. This does not constitute a sign of deterioration.

The vaccine should be shaken well to obtain a homogeneous white suspension prior to expelling air from the syringe, and should be inspected visually for any particulate matter and/or variation of physical aspect prior to administration. Do not use if the content appears otherwise.

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MANUFACTURER

Beijing Minhai Biotechnology Co., Ltd.

No.35, Simiao Road, Bioengineering & Pharmaceutical Industrial Park, Daxing District, Beijing,

China.

8. MARKETING AUTHORIZATION HOLDER

PT Jakarta Biopharmaceutical Industry
Jl. Musi No. 15, Cideng, Gambir, Jakarta, Indonesia

9. MARKETING AUTHORIZATION NUMBER

HARUS DENGAN RESEP DOKTER

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

In the production stage, porcine-derived material was used. There is no detectable porcine DNA in the final product.

Informasi Obat untuk Pasien

PNEUMINVAC

PCV 13 Suspensi untuk Injeksi

13-valent Pneumococcal Polysaccharide Conjugate Vaccine
(TT/DT)

Baca semua selebaran ini dengan seksama sebelum Anda atau anak Anda menerima vaksin ini karena berisi informasi penting bagi Anda.

- Simpan selebaran ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda .
- Vaksin ini telah diresepkan untuk Anda atau anak Anda saja. Jangan memberikannya kepada orang lain.
- Jika Anda atau anak Anda mendapatkan efek samping, bicarakan dengan dokter, apoteker, atau perawat Anda. Ini termasuk kemungkinan efek samping yang tidak tercantum dalam selebaran ini. Lihat bagian 4.

Apa yang ada di selebaran ini?

1. Apa itu PCV 13 dan untuk apa itu digunakan?

PCV 13 adalah vaksin pneumokokus yang diberikan kepada bayi dan anak-anak dari usia 6 minggu hingga 5 tahun (sebelum ulang tahun ke-6) untuk membantu melindungi dari penyakit yang disebabkan bakteri S. Pneumoniae serotipe serotipe (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A , 19F dan 23F).

2. Apa yang perlu Anda ketahui sebelum Anda atau anak Anda menerima PCV 13

PCV 13 tidak boleh diberikan

- jika anak Anda alergi (hipersensitif) terhadap zat aktif atau bahan-bahan yang lainnya dalam obat ini (tercantum dalam Bagian 6) atau vaksin lain yang mengandung toksoid difteri .
- jika anak Anda mengalami infeksi parah dengan suhu tinggi (lebih dari 38°C). Jika ini berlaku untuk anak Anda, maka vaksinasi akan ditunda sampai Anda atau anak Anda merasa lebih baik. Infeksi ringan, seperti pilek, seharusnya tidak menjadi masalah. Namun, bicarakan dengan dokter, apoteker, atau perawat Anda terlebih dahulu.

Peringatan dan tindakan pencegahan

Bicaralah dengan dokter, apoteker, atau perawat Anda sebelum vaksinasi jika anak Anda:

- memiliki masalah medis pada saat ini atau pada masa lalu setelah penerimaan dosis PCV13 seperti reaksi alergi atau masalah dengan pernapasan.
- memiliki masalah pendarahan atau memar dengan mudah.
- memiliki sistem kekebalan tubuh yang lemah (misalnya, *malignancy* atau sindrom nefrotik), dia mungkin tidak mendapatkan manfaat penuh dari PCV 13.
- pernah mengalami demam, penyakit akut, dan serangan akut dari penyakit kronis.

Bicaralah dengan dokter, apoteker, atau perawat Anda sebelum vaksinasi jika anak Anda lahir prematur.

Seperti halnya vaksin apa pun, PCV 13 tidak akan melindungi semua orang yang divaksinasi. PCV 13 hanya akan melindungi terhadap infeksi pada anak-anak yang disebabkan oleh jenis *Streptococcus pneumoniae* yang vaksinnya telah dikembangkan. Ini tidak akan melindungi terhadap agen infeksi lain yang dapat menyebabkan infeksi.

Obat/vaksin lain dan PCV 13

Dokter Anda mungkin meminta Anda untuk memberikan parasetamol atau obat-obatan lain yang menurunkan demam sebelum PCV 13 diberikan. Ini akan membantu menurunkan beberapa efek samping PCV 13.

Mengemudi dan menggunakan mesin

PCV 13 tidak memiliki pengaruh atau dapat diabaikan pada kemampuan untuk mengemudi dan menggunakan mesin. Namun, beberapa efek yang disebutkan di bawah bagian 4 "Kemungkinan efek samping" sementara dapat mempengaruhi kemampuan untuk mengemudi atau menggunakan mesin.

PCV 13 mengandung natrium

Produk obat ini mengandung kurang dari 1 mmol natrium (23 mg) per dosis, yaitu pada dasarnya 'bebas natrium'

3. Bagaimana PCV 13 diberikan

Dokter atau perawat akan menyuntikkan dosis vaksin yang disarankan (0,5 ml) ke otot lengan Anda atau otot lengan atau otot kaki anak Anda (intramuscular). Tempat suntikan yang direkomendasikan untuk bayi adalah paha anterolateral. Tempat suntikan yang direkomendasikan untuk balita dan anak-anak adalah otot deltoid luar lengan atas.

Bayi berusia 2 ~ 6 bulan

Biasanya, anak Anda harus menerima rangkaian awal tiga suntikan vaksin diikuti dengan dosis *booster*.

- Suntikan pertama dapat diberikan sejak usia 2 bulan (setidaknya usia 6 minggu).
- Setiap suntikan akan diberikan setidaknya dua bulan terpisah.

- Suntikan keempat (*booster*) akan diberikan antara usia 12 dan 15 bulan.
- Anda akan diberi tahu kapan anak Anda harus kembali untuk suntikan berikutnya.

Menurut rekomendasi resmi di negara Anda, jadwal alternatif dapat digunakan oleh penyedia layanan kesehatan Anda. Silakan berbicara dengan dokter, apoteker, atau perawat Anda untuk informasi lebih lanjut.

Bayi berusia 7~11 bulan

Anak Anda akan menerima rangkaian awal tiga suntikan. Suntikan pertama dapat diberikan sejak usia enam minggu dengan setidaknya satu bulan antara dosis. Setelah usia 12 bulan, anak Anda akan menerima suntikan keempat (*booster*).

Balita berusia 12 ~ 23 bulan

Balita berusia 12 ~ 23 bulan harus menerima dua suntikan. Setiap suntikan akan diberikan setidaknya dua bulan terpisah.

Anak-anak berusia 24 bulan ~ 5 tahun

Anak-anak berusia 24 bulan hingga 5 tahun harus menerima satu suntikan.

4. Kemungkinan efek samping

Seperti semua vaksin, PCV 13 dapat menyebabkan efek samping, meskipun tidak semua orang mendapatkannya.

Efek samping berikut termasuk yang dilaporkan untuk PCV 13 pada bayi dan anak-anak (usia 2 bulan hingga 5 tahun):

2 ~ 6 bulan

① Efek samping sistemik

Sangat umum: demam, menangis.
Umum: batuk, diare, muntah, kehilangan nafsu makan, kelelahan.
Sesekali: infeksi saluran pernapasan atas.

② Efek samping lokal

Sangat umum: kemerahan, bengkak, indurasi.
Umum: Nyeri.
Sesekali: ruam (tempat suntikan).

③ Efek samping serius

Satu kasus efek samping serius (SAE) terjadi selama fase imunisasi booster dari uji klinis fase III produk ini pada kelompok berusia 2 bulan adalah kejang demam dan infeksi saluran pernapasan atas akut, yang ditentukan mungkin terkait dengan produk ini, dan efek samping serius lainnya tidak terkait dengan produk ini.

7 bulan ~ 5 tahun

① Efek samping sistemik

Sangat umum: demam.
Umum: menangis, diare, batuk, muntah, kehilangan nafsu makan, kelelahan.
Sesekali: mialgia, sakit kepala, alergi dermatitis.

② Efek samping lokal

Sangat umum: kemerahan.
Umum: pembengkakan, indurasi, nyeri.
Sesekali: gatal, ruam (tempat suntikan), kelainan kulit dan mukosa.

Pelaporan efek samping

Jika anak Anda mendapat efek samping, bicarakan dengan tenaga kesehatan dokter, apoteker, atau perawat Anda. Ini termasuk kemungkinan efek samping yang tidak tercantum dalam selebaran ini.

Dengan melaporkan efek samping, Anda dapat membantu memberikan informasi lebih lanjut tentang keamanan obat ini.

5. Cara menyimpan PCV 13

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan gunakan obat ini setelah tanggal kedaluwarsa yang tertera pada karton dan label setelah EXP. Tanggal kedaluwarsa mengacu pada hari terakhir bulan itu.

Simpan dan kirim pada suhu 2-8 °C, lindungi dari cahaya. Jangan dibekukan.

Jangan membuang obat-obatan melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda bagaimana cara membuang obat-obatan yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi produk dan informasi lainnya

1 dosis (0.5 ml) mengandung:

Pneumococcal polysaccharides serotype 1 1.8 ug	Pneumococcal polysaccharides serotype 9V 2.3 ug
Pneumococcal polysaccharides serotype 3 2.1 ug	Pneumococcal polysaccharides serotype 14 1.35 ug
Pneumococcal polysaccharides serotype 4 2.1 ug	Pneumococcal polysaccharides serotype 18C 3.65 ug
Pneumococcal polysaccharides serotype 5 1.75 ug	Pneumococcal polysaccharides serotype 19A 1.6 ug

Pneumococcal polysaccharides serotype 6A 1.85 ug	Pneumococcal polysaccharides serotype 19F 1.25 ug
Pneumococcal polysaccharides serotype 6B 4.4 ug	Pneumococcal polysaccharides serotype 23F 2.35 ug
Pneumococcal polysaccharides serotype 7F 1.75 ug	

Produk ini menggunakan antigen polisakarida kapsular dari serotipe streptococcus pneumonia 1, 5, 6A, 9V, 19A, 19F, dan 23F dikombinasikan secara kovalen dengan toksoid tetanus murni untuk membentuk konjugat protein polisakarida. Antigen polisakarida kapsular dari serotipe streptococcus pneumonia 3, 4, 6B, 7F, 14 dan 18C secara kovalen dikombinasikan dengan toksoid difteri murni untuk membentuk konjugat protein polisakarida, dan kemudian 13 jenis konjugat protein polisakarida dicampur dalam proporsi tertentu dan kemudian diserap dengan adjuvan aluminium fosfat.

Bahan lainnya adalah natrium oksida, asam suksinat, polisorbat 80, aluminium fosfat.

Seperti apa bentuk PCV 13 dan isi produknya?

Vaksin ini adalah suspensi putih untuk injeksi, disediakan dalam dosis tunggal, jarum suntik yang sudah diisi (*pre-filled syringe*) (0,5 ml). Ukuran kemasan adalah:

Dus, 1 *syringe* @ 0,5 ml

Nomor Ijin Edar

Produsen

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HARUS DENGAN RESEP DOKTER

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

Pada tahap produksi, bahan turunan babi digunakan. Tidak ada DNA babi yang terdeteksi dalam produk akhir.