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WALVAX 沃森生物®
Yuxi Walvax Biotechnology Co.,Ltd.

Package Insert
23-valent Pneumococcal Polysaccharide Vaccine

Please read the package insert carefully and follow the physician's guidance to use.

1 PRODUCT NAME

Generic name: 23-valent Pneumococcal Polysaccharide Vaccine

2 PRODUCT DESCRIPTION

The 23-valent Pneumococcal Polysaccharide Vaccine (PPSV23) is a sterile liquid vaccine consisting 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). No preservatives are added. This vaccine is supplied as a single-dose, pre-filled syringe. This vaccine is presented as a clear and colorless solution.

Active substances: capsular polysaccharides of *Streptococcus pneumoniae* types 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19A, 19F, 20, 22F, 23F, and 33F.

Excipients: sodium dihydrogen phosphate 30 μg, disodium hydrogen phosphate 35.5 μg, and sodium chloride 4.25 mg.

Pneumococcal polysaccharide serotype 1	25 μg	Pneumococcal polysaccharide serotype 12F	25 μg
Pneumococcal polysaccharide serotype 2	25 μg	Pneumococcal polysaccharide serotype 14	25 μg
Pneumococcal polysaccharide serotype 3	25 μg	Pneumococcal polysaccharide serotype 15B	25 μg
Pneumococcal polysaccharide serotype 4	25 μg	Pneumococcal polysaccharide serotype 17F	25 μg
Pneumococcal polysaccharide serotype 5	25 μg	Pneumococcal polysaccharide serotype 18C	25 μg
Pneumococcal polysaccharide serotype 6B	25 μg	Pneumococcal polysaccharide serotype 19A	25 μg
Pneumococcal polysaccharide serotype 7F	25 μg	Pneumococcal polysaccharide serotype 19F	25 μg
Pneumococcal polysaccharide serotype 8	25 μg	Pneumococcal polysaccharide serotype 20	25 μg
Pneumococcal polysaccharide serotype 9N	25 μg	Pneumococcal polysaccharide serotype 22F	25 μg
Pneumococcal polysaccharide serotype 9V	25 μg	Pneumococcal polysaccharide serotype 23F	25 μg
Pneumococcal polysaccharide serotype 10A	25 μg	Pneumococcal polysaccharide serotype 33F	25 μg
Pneumococcal polysaccharide serotype 11A	25 μg		

3 INDICATION

The vaccine is indicated for using in individuals aged ⩾ 2 years who are at increased risk of pneumococcal disease.

The vaccine elicits immune response in recipients following immunization and is indicated for the prevention of pneumococcal diseases 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). The vaccine will not prevent diseases caused by capsular types of *Streptococcus pneumoniae* other than those contained in the vaccine.

4 NAME AND STRENGTH OF ACTIVE SUBSTANCES

The vaccine is supplied in a single-dose, prefilled syringe with 0.5 mL solution for intramuscular or subcutaneous injection. Each one dose (0.5 mL) of PPSV23 contains:

5 DOSAGE AND ADMINISTRATION

5.1 Injection Site and Route of Administration

This product is for intramuscular or subcutaneous injection (intramuscularly recommended) and the preferred administration site is the deltoid muscle of the lateral upper arm or lateral mid-thigh. Intravascular and intradermal injection is prohibited.

5.2 Dosage

Single dose (0.5 mL).

5.3 Revaccination

Persons at high risk (splenectomy) who were previously vaccinated over 5 years or with significant decreasing antibody titers (e.g., nephrotic syndrome, renal failure and organ transplantation) are recommended to revaccinate against pneumococcal diseases.

Children under 10 years old with nephrotic syndrome, splenectomy or sickle cell diseases are recommended to revaccinate 3-5 years later after the initial vaccination.

The immune persistence of this product has so far not demonstrated by any clinical study. The recommendations for revaccination above are compiled based on the recommendations for subsequent doses of PPSV23 prescribed in the *Prevention of Pneumococcal Diseases-Recommendations by the Advisory Committee on Immunization Practices* (CDC, United States, 1997).

6 ADVERSE REACTIONS

6.1 Clinical Trial Experience with PPSV23

Two clinical trials (phase I and III) of PPSV23 were conducted in China, including 60 and 1660 subjects, respectively. Among all subjects (N=1720), subjects included in phase I clinical trial (N=60) and subjects in the PPSV23 group of phase III clinical trial (N=830) were administered with one dose of PPSV23. All subjects were observed for 30 minutes after immunization at the investigation site, and the investigator actively collected the systemic and local reactions through Day 0 to Day 7 after immunization. The adverse events/reactions were reported by the subjects or collected by regular follow-up from Day 8 to Day 30 post immunization.

6.1.1 Summary

The incidence rates of adverse reactions reported in clinical trials, according to the guidance on classifications of adverse events recommended by the Council for International Organizations of Medical Sciences (CIOMS), are classified as:

very common (⩾10%), common (⩾1% to <10%), uncommon (⩾0.1% to <1%), rare (⩾0.01% to <0.1%), and very rare (<0.01%) as follows:

Very common:
(1) Local reaction(s): pain.
Common:
(1) Local reactions: redness, swelling, itching.
(2) Systemic reactions: fever, fatigue, headache, diarrhea.
Uncommon:
(1) Local reaction(s): induration.
(2) Systemic reactions: vomiting, rash, allergy.

6.1.2 Adverse Reactions in Phase III Clinical Trial

(1) Incidence rates and severity of solicited adverse reactions by age groups

The incidence rates and severity of solicited adverse reactions post immunization in phase III clinical trial of PPSV23 in comparison to the comparator vaccine PNEUMOVAX®23 (pneumococcal vaccine polyvalent) manufactured by Merck Sharp & Dohme Ltd., (referred to as PNEUMOVAX®23) are summarized in Table 1 and Table 2.

Table 1 Incidence Rates and Severity of Solicited Local Adverse Reactions Related to Study Vaccines in Phase III Clinical Trial Conducted in China

Symptoms and Grading of Local Adverse Reactions	2-6 Years					7-17 Years					18-59 Years					60 Years and Above				
	PPSV23 (N*=125)		PNEUMOVAX®23 (N*=125)		P#	PPSV23 (N*=125)		PNEUMOVAX®23 (N*=125)		P#	PPSV23 (N*=330)		PNEUMOVAX®23 (N*=330)		P#	PPSV23 (N*=250)		PNEUMOVAX®23 (N*=250)		P#
	n**	%&	n**	%&		n**	%&	n**	%&		n**	%&	n**	%&		n**	%&	n**	%&	
Local Pain																				
Grade 1	24	19.20	19	15.20	0.5399	28	22.40	34	27.20	0.8043	91	27.58	94	28.48	0.5823	30	12.00	29	11.60	0.8957
Grade 2	1	0.80	2	1.60		10	8.00	4	3.20		14	4.24	17	5.15		3	1.20	3	1.20	
Grade 3	0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Total	25	20.00	21	16.80		38	30.40	38	30.40		105	31.82	111	33.64		33	13.20	32	12.80	
Local Redness																				
Grade 1	5	4.00	4	3.20	0.5592	3	2.40	3	2.40	0.1309	8	2.42	11	3.33	0.0474	5	2.00	4	1.60	0.7821
Grade 2	1	0.80	4	3.20		4	3.20	2	1.60		12	3.64	19	5.76		2	0.80	3	1.20	
Grade 3	0	0.00	0	0.00		5	4.00	1	0.80		5	1.52	10	3.03		0	0.00	1	0.40	
Total	6	4.80	8	6.40		12	9.60	6	4.80		25	7.58	40	12.12		7	2.80	8	3.20	
Local Swelling																				
Grade 1	2	1.60	3	2.40	0.4058	5	4.00	4	3.20	0.0893	6	1.82	10	3.03	0.0654	4	1.60	2	0.80	0.4655
Grade 2	0	0.00	0	0.00		6	4.80	3	2.40		8	2.42	12	3.64		3	1.20	6	2.40	
Grade 3	0	0.00	1	0.80		6	4.80	2	1.60		3	0.91	7	2.12		1	0.40	3	1.20	
Total	2	1.60	4	3.20		17	13.60	9	7.20		17	5.15	29	8.79		8	3.20	11	4.40	
Local Itching																				
Grade 1	4	3.20	1	0.80	0.1762	1	0.80	3	2.40	0.3144	11	3.33	6	1.82	0.2463	3	1.20	3	1.20	0.7004
Grade 2	0	0.00	0	0.00		0	0.00	0	0.00		1	0.30	1	0.30		0	0.00	1	0.40	
Grade 3	0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Total	4	3.20	1	0.80		1	0.80	3	2.40		12	3.64	7	2.12		3	1.20	4	1.60	
Local Induration																				
Grade 1	0	0.00	0	0.00	/	0	0.00	0	0.00	/	0	0.00	0	0.00	/	1	0.40	0	0.00	0.3173
Grade 2	0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Grade 3	0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Total	0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		1	0.40	0	0.00	
Any Local Reactions																				
Grade 1	24	19.20	19	15.20	0.9831	21	16.80	32	25.60	0.6200	75	22.73	70	21.21	0.2175	29	11.60	21	8.40	0.7801
Grade 2	2	1.60	5	4.00		11	8.80	6	4.80		24	7.27	35	10.61		6	2.40	9	3.60	
Grade 3	0	0.00	1	0.80		8	6.40	2	1.60		6	1.82	11	3.33		1	0.40	3	1.20	
Total	26	20.80	25	20.00		40	32.00	40	32.00		105	31.82	116	35.15		36	14.40	33	13.20	

Note: adverse events included in this table were all determined as related to the study vaccine ("related to the vaccine" was defined as the correlation between the adverse event and the study vaccine was possibly related, probably related or definitely related). When the same adverse event occurs to a certain subject for multiple times, the one with the highest severity was recorded as the corresponding event in this table.

* N = number of subjects included in the safety analysis for each group.
** n = number of subjects reported for each reaction in each group.
& % = n/N*100%.
# The P value was obtained by two-sided Kruskal-Wallis test.

Table 2 Incidence Rates and Severity of Solicited Systemic Adverse Reactions Related to Study Vaccines in Phase III Clinical Trial Conducted in China

Symptoms and Grading of Systemic Adverse Reactions	2-6 Years					7-17 Years					18-59 Years					60 Years and Above				
	PPSV23 (N*=125)		PNEUMOVAX® 23 (N*=125)		P#	PPSV23 (N*=125)		PNEUMOVAX® 23 (N*=125)		P#	PPSV23 (N*=330)		PNEUMOVAX® 23 (N*=330)		P#	PPSV23 (N*=250)		PNEUMOVAX® 23 (N*=250)		P#
	n**	%&	n**	%&		n**	%&	n**	%&		n**	%&	n**	%&		n**	%&	n**	%&	
Fever																				
Grade 1	10	8.00	11	8.80	0.7017	16	12.80	19	15.20	0.2970	26	7.88	27	8.18	0.8755	10	4.00	8	3.20	0.8545
Grade 2	4	3.20	5	4.00		3	2.40	6	4.80		6	1.82	6	1.82		4	1.60	5	2.00	
Grade 3	1	0.80	1	0.80		0	0.00	0	0.00		2	0.61	0	0.00		0	0.00	0	0.00	
Total	15	12.00	17	13.60		19	15.20	25	20.00		34	10.30	33	10.00		14	5.60	13	5.20	
Headache																				
Grade 1	0	0.00	1	0.80	0.3173	3	2.40	3	2.40	0.7287	11	3.33	18	5.45	0.2287	5	2.00	4	1.60	0.9949
Grade 2	0	0.00	0	0.00		1	0.80	2	1.60		3	0.91	3	0.91		0	0.00	1	0.40	
Grade 3	0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Total	0	0.00	1	0.80		4	3.20	5	4.00		14	4.24	21	6.36		5	2.00	5	2.00	
Fatigue																				
Grade 1	0	0.00	3	2.40	0.0820	6	4.80	5	4.00	0.3813	14	4.24	13	3.94	0.4584	6	2.40	2	0.80	0.2036
Grade 2	0	0.00	0	0.00		2	1.60	0	0.00		1	0.30	6	1.82		1	0.40	1	0.40	
Grade 3	0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Total	0	0.00	3	2.40		8	6.40	5	4.00		15	4.55	19	5.76		7	2.80	3	1.20	
Nausea and Vomiting																				
Grade 1	0	0.00	3	2.40	0.0820	0	0.00	1	0.80	0.1565	4	1.21	5	1.52	0.9962	0	0.00	2	0.80	0.5660
Grade 2	0	0.00	0	0.00		0	0.00	1	0.80		1	0.30	0	0.00		1	0.40	0	0.00	
Grade 3	0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Total	0	0.00	3	2.40		0	0.00	2	1.60		5	1.52	5	1.52		1	0.40	2	0.80	
Diarrhea																				
Grade 1	0	0.00	1	0.80	0.3173	2	1.60	3	2.40	0.9921	3	0.91	3	0.91	0.7016	2	0.80	2	0.80	0.6508
Grade 2	0	0.00	0	0.00		1	0.80	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Grade 3	0	0.00	0	0.00		0	0.00	0	0.00		1	0.30	0	0.00		0	0.00	1	0.40	
Total	0	0.00	1	0.80		3	2.40	3	2.40		4	1.21	3	0.91		2	0.80	3	1.20	

Rash																				
Grade 1	1	0.80	2	1.60	0.6547	1	0.80	2	1.60	0.3125	1	0.30	1	0.30	1.0000	1	0.40	0	0.00	0.3173
Grade 2	1	0.80	1	0.80		0	0.00	1	0.80		0	0.00	0	0.00		0	0.00	0	0.00	
Grade 3	0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Total	**2**	**1.60**	**3**	**2.40**		**1**	**0.80**	**3**	**2.40**		**1**	**0.30**	**1**	**0.30**		**1**	**0.40**	**0**	**0.00**	
Hypersensitivity																				
Grade 1	1	0.80	0	0.00	0.5621	0	0.00	0	0.00	/	0	0.00	0	0.00	/	0	0.00	0	0.00	/
Grade 2	0	0.00	1	0.80		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Grade 3	1	0.80	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00		0	0.00	0	0.00	
Total	**2**	**1.60**	**1**	**0.80**		**0**	**0.00**	**0**	**0.00**		**0**	**0.00**	**0**	**0.00**		**0**	**0.00**	**0**	**0.00**	
Any Systemic Reactions																				
Grade 1	11	8.80	16	12.80	0.3348	22	17.60	28	22.40	0.1872	39	11.82	44	13.33	0.6202	17	6.80	15	6.00	0.9754
Grade 2	5	4.00	7	5.60		6	4.80	9	7.20		9	2.73	12	3.64		5	2.00	6	2.40	
Grade 3	2	1.60	1	0.80		0	0.00	0	0.00		3	0.91	0	0.00		0	0.00	1	0.40	
Total	**18**	**14.40**	**24**	**19.20**		**28**	**22.40**	**37**	**29.60**		**51**	**15.45**	**56**	**16.97**		**22**	**8.80**	**22**	**8.80**	

Note: adverse events included in this table were all determined as related to the study vaccine ("related to the vaccine" was defined as the correlation between the adverse event and the study vaccine was possibly related, probably related or definitely related). When the same adverse event occurs to a certain subject for multiple times, the one with the highest severity was recorded as the corresponding event in this table.

* N = number of subjects included in the safety analysis for each group.

** n = number of subjects reported for each reaction in each group.

& % = n/N*100%.

\# The P value was obtained by two-sided Kruskal-Wallis test.

(2) Incidence rate and severity of unsolicited adverse reactions

The overall incidence rate of unsolicited adverse reactions reported by subjects in the PPSV23 group of Phase III clinical trial for PPSV23 was 3.98% (33 cases among 830 subjects). The most common unsolicited adverse event was respiratory disease. The incidence of influenza/upper respiratory tract infection in PPSV23 group and PNEUMOVAX®23 group was 2.53% and 2.77%, respectively. No significant difference was observed in the incidence of each unsolicited adverse event between PPSV23 group and PNEUMOVAX®23 group. The documented symptoms include: influenza/upper respiratory tract infection, tonsillitis, pharyngitis, bronchitis, gastrorrhagia, gastroenteritis, vomiting, trauma, myalgia, stomatitis, toothache, systemic pruritus, keratitis, hand-foot-mouth disease, osteoproliferation, thyrophyma, cervical spondylosis, cerebral infarction, dizziness, gynecologic surgery etc.

6.2 Post-marketing Experience with PPSV23

The following adverse events have been reported through passive surveillance since the launch of the PPSV23. Considering that these events were reported voluntarily from a population of an uncertain size, the frequency of the events is not always possible to be reliably estimated and the causal relationship between the events and vaccination cannot be established due to the same reason.

The following adverse events were collected based on one or more of the undermentioned elements: frequency of reporting, severity, or strength of evidence for a causal relationship to PPSV23.

General disorders and administration site: fever, injection site swelling, injection site erythema, vaccination site induration.

Skin and subcutaneous tissue disorders: localized erythema, allergic rash, urticaria.

Immune system disorders: allergic reaction.

Infections and infestations: infection upper respiratory.

Nervous system disorders: fever convulsions.

If any adverse reactions not included above occur after administering this vaccine, please contact and report to your physician.

7 CONTRAINDICATIONS

This vaccine should not be administered to:

(1) Individuals with allergic reactions to any component of the vaccine.

(2) Individuals with encephalopathy, uncontrolled epilepsy, or other progressive diseases of the nervous system.

(3) Individuals with fever, acute infection, or chronic diseases at the acute stage.

(4) Only if clearly needed, otherwise revaccination within 3 years is not recommended.

8 PRECAUTIONS

(1) Do not administer intracutaneously or intravenously, and ensure the syringe needle is not puncturing blood vessels during inoculation.

(2) The vaccine shall be administered with caution to nursing women or individuals with family or individual history of convulsion, history of epilepsy and allergic diathesis.

(3) Check if the package, container, label, appearance and expiration date of the vaccine follow corresponding requirements before administration. Do not use the vaccine in case that any crack is observed in the container, loosened stopper, detached label, particulate matter or discoloring inside the container, etc. Do not use the vaccine after the expiration date.

(4) Use immediately after unsealing. A single human dose shall be used up each time according to prescribed information.

(5) Appropriate monitoring, medical care and rescue measures should be readily available in case of rare hypersensitivity reactions during vaccination. The recipient shall be observed for at least 30 minutes on site following injection.

(6) If allergic reactions occur after vaccination, please visit the vaccination site or hospital in time.

(7) Do not freeze. Discard if the vaccine has been frozen.

9 USE IN SPECIFIC POPULATIONS

9.1 Pregnancy

Administering this vaccine in pregnant women is not recommended. Administration of the vaccine in this population is determined by doctors based on the risk faced with the potential recipients.

9.2 Lactation

Administration of the vaccine in nursing mothers should be determined by doctors with caution.

9.3 Pediatric Use

Do not administer the vaccine to children below 2 years of age.

10 INTERACTIONS WITH OTHER MEDICAMENTS

No clinical data of this product co-administered with other vaccines inside or outside China are available. As per the information available for other similar marketed vaccines, PPSV23 may be administered at the same time with influenza vaccine by separate injection in the other arm.

Any medications, being or having recently been administered, including OTCs, should be reported to the physician.

11 OVERDOSE AND TREATMENT

Overdose with PPSV23 is unlikely due to its presentation as a single-dose pre-filled syringe. No overdose data are currently available for the product in recipients.

12 PHARMACODYNAMIC/PHARMACOKINETICS

Not applicable.

13 CLINICAL TRIALS

The safety and immunogenicity of this vaccine were evaluated in a phase III, randomized, double-blind and non-inferiority study designed with a positive control of imported similar vaccine. The blood samples were collected pre-immunization as well as on Day 30 and 35 post-immunization, respectively. The ELISA assay was used to detect the pneumococcal antibody concentrations of 23 serotypes. The percentages of subjects with 2-fold increase in the antibody concentrations of each serotype were compared to those obtained pre-immunization for both the PPSV23 group and the PNEUMOVAX®23 group. The overall percentage of subjects with 2-fold increase in the antibody concentrations of all 23 serotypes and the geometric mean antibody concentrations (GMCs) were also determined.

A total of 1660 subjects were enrolled in the phase III study, among which 1619 cases (97.53%) completed all study procedures, and 41 cases (2.47%) dropped out, resulting in 1619 cases (97.53%) included in the Full Analysis Set (FAS), and 1606 cases (96.75%) in the Per-Protocol Set (PPS). All subjects were involved in the safety analysis. FAS was determined as the primary analysis set, and the results obtained from FAS were basically consistent with those from PPS (Table 3 and Table 4).

Table 3 Percentages of Subjects with 2-fold Increase in Antibody Concentrations for the PPSV23 and PNEUMOVAX®23 Groups Post-immunization (FAS)

Serotype	PPSV23 Group (N=811)			PNEUMOVAX®23 (N=808)			Difference % (one-sided 97.5% CI)	P
	n	%	95% CI	n	%	95% CI		
1	534	65.84	62.47-69.11	539	66.71	63.34-69.95	-0.86(-5.47, ∞)	0.7133
2	726	89.52	87.20-91.54	692	85.64	83.03-87.99	4.20(1.02, ∞)	0.0097
3	582	71.76	68.53-74.84	498	61.63	58.18-65.00	10.13(5.56, ∞)	<0.0001
4	661	81.50	78.66-84.12	580	71.78	68.54-74.86	9.72(5.63, ∞)	<0.0001
5	544	67.08	63.72-70.31	541	66.96	63.59-70.19	0.12(-4.46, ∞)	0.9583
6B	525	64.73	61.34-68.03	567	70.17	66.89-73.31	-5.44(-10.00, ∞)	0.0195
7F	621	76.57	73.50-79.45	630	77.97	74.95-80.78	-1.40(-5.48, ∞)	0.5021
8	764	94.20	92.37-95.71	767	94.93	93.18-96.33	-0.72(-2.93, ∞)	0.5223
9N	786	96.92	95.48-98.00	772	95.54	93.88-96.86	1.37(-0.48, ∞)	0.1469
9V	722	89.03	86.67-91.09	712	88.12	85.69-90.27	0.91(-2.19, ∞)	0.5662
10A	536	66.09	62.72-69.35	415	51.36	47.85-54.86	14.73(9.99, ∞)	<0.0001
11A	612	75.46	72.35-78.39	567	70.17	66.89-73.31	5.29(0.96, ∞)	0.0168
12F	598	73.74	70.56-76.74	616	76.24	73.15-79.13	-2.50(-6.72, ∞)	0.2452
14	502	61.90	58.46-65.25	489	60.52	57.05-63.91	1.38(-3.37, ∞)	0.5691
15B	627	77.31	74.27-80.15	606	75.00	71.86-77.95	2.31(-1.84, ∞)	0.2750
17F	685	84.46	81.78-86.89	701	86.76	84.22-89.02	-2.29(-5.71, ∞)	0.1886
18C	733	90.38	88.14-92.32	732	90.59	88.37-92.52	-0.21(-3.07, ∞)	0.8845
19A	568	70.04	66.75-73.17	574	71.04	67.78-74.15	-1.00(-5.44, ∞)	0.6582
19F	602	74.23	71.07-77.21	615	76.11	73.02-79.02	-1.88(-6.09, ∞)	0.3802
20	665	82.00	79.18-84.58	621	76.86	73.79-79.72	5.14(1.21, ∞)	0.0105
22F	539	66.46	63.09-69.71	521	64.48	61.07-67.78	1.98(-2.65, ∞)	0.4019
23F	526	64.86	61.46-68.15	515	63.74	60.32-67.06	1.12(-3.55, ∞)	0.6380
33F	783	96.55	95.05-97.69	770	95.30	93.60-96.65	1.25(-0.68, ∞)	0.2033

Table 4 GMCs of the PPSV23 and PNEUMOVAX®23 Groups Post-immunization (FAS)

Serotype	PPSV23 Group (N=811)		PNEUMOVAX®23 (N=808)		P
	GMC	95% CI	GMC	95% CI	
1	45.69	42.84-48.73	45.16	42.22-48.29	0.8039
2	121.01	111.87-130.89	102.61	94.91-110.94	0.0035
3	155.10	144.75-166.18	117.99	110.58-125.89	<0.0001
4	103.62	97.04-110.64	76.62	71.89-81.66	<0.0001
5	79.60	74.98-84.51	77.43	73.02-82.12	0.5177
6B	17.27	15.07-19.79	21.63	19.03-24.58	0.0183
7F	154.62	145.51-164.31	158.09	148.61-168.18	0.6158
8	110.58	103.34-118.33	110.86	103.35-118.92	0.9595
9N	91.21	85.33-97.50	88.53	82.70-94.77	0.5387
9V	112.21	104.31-120.71	89.31	82.84-96.28	<0.0001
10A	96.98	89.43-105.17	64.55	59.99-69.45	<0.0001
11A	103.84	97.90-110.14	91.53	86.17-97.22	0.0034
12F	153.70	141.80-166.60	153.91	140.42-168.68	0.9829
14	73.45	68.27-79.01	77.34	72.08-83.00	0.3179
15B	155.20	144.74-166.42	135.45	126.63-144.87	0.0059
17F	109.81	103.02-117.05	108.94	102.40-115.90	0.8606
18C	72.27	67.20-77.73	64.11	59.76-68.78	0.0202
19A	129.03	119.09-139.81	111.73	103.15-121.03	0.0127
19F	115.10	106.03-124.94	110.70	102.02-120.12	0.5089
20	152.95	142.27-164.44	137.14	125.03-150.42	0.0682
22F	118.73	111.93-125.94	108.63	102.55-115.06	0.0342
23F	85.16	79.03-91.78	80.88	74.90-87.35	0.3455
33F	114.16	106.35-122.54	92.52	86.31-99.17	<0.0001

14 STORAGE CONDITION

Transport and store refrigerated at 2°C to 8°C, protect from light.

DO NOT FREEZE. Discard if the vaccine has been frozen.

Keep the product out of children's reach.

15 DOSAGE FORMS AND PACKAGING AVAILABLE

Pre-filled syringe, 1×0.5 mL single human dose, 1 syringe per package.

16 INCOMPATIBILITIES

This vaccine should not be mixed with other medicinal products considering that no compatibility studies have been conducted.

17 SHELF LIFE

The shelf life of the vaccine is 24 months. Please use before the expiration date printed on the label or small box.

18 APPROVAL NUMBER

National Medical Products Administration Drug Registration Certificate No. GuoYaoZhunZi S20170003

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