Approval Date:
Revision Date:

Recombinant COVID-19 Vaccine (Sf9 cell) Package Insert

Please read the package insert carefully and use under the guidance of the physician

[NAME OF THE MEDICINAL PRODUCT]

Generic Name: Recombinant COVID-19 Vaccine (Sf9 cell)
Trade Name: Coviccine®
English Name: Recombinant COVID-19 Vaccine (Sf9 cell)
Chinese Phonetic Alphabet: Chongzu Xinxing Guanzhuang Bingdu Yimiao (Sf9 Xibao)

[COMPOSITION]

This product is produced by the receptor-binding domain of SARS-CoV-2 spike protein (S-RBD) which is expressed by using a baculovirus vector in Sf9 cell, followed by protein isolation, purification and aluminum hydroxide adsorption. This product does not contain preservatives or antibiotics.
Active ingredient: Recombinant SARS-CoV-2 S-RBD protein.
Adjuvant: Aluminum hydroxide.
Excipients: Disodium hydrogen phosphate, sodium dihydrogen phosphate, sodium chloride.

[APPEARANCE]

Suspension for injection (intramuscular injection).
The product is a milky-white suspension. Stratified precipitate may form which can be dispersed by shaking.

[TARGET GROUPS FOR VACCINATION]

Individuals 18 years of age and older.

[THERAPEUTIC INDICATION]

The product is indicated for active immunization to prevent coronavirus (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

[STRENGTHS]

Each vial contains 1.0 mL. Single dose of 1.0 mL contains 40 μg of recombinant SARS-CoV-2 S-RBD protein.

[ADMINISTRATION AND DOSAGE]

1. Primary series: This product is to be administered as a series of 3 doses 3-4 weeks apart. 40 μg (1.0 mL) per dose.
2. Booster doses: a booster dose of 40 μg (1.0 mL) to individuals 3~6 months after completion of primary immunization of COVID-19 vaccine.

3. Booster doses: a single dose of 40 μg (1.0 mL) to individuals 3~6 months after receipt of the 1st booster dose of COVID-19 vaccine.
4. Or adhere to the booster vaccination schedule in the immunization program developed by the National Disease Control and Prevention Administration People's Republic of China.
5. The product should be administered by intramuscular injection in the deltoid region of the upper arm. Shake well before use.

[ADVERSE REACTIONS]

The safety of this product was evaluated in five clinical trials within and outside China: A randomized, double-blinded, placebo-controlled Phase I clinical trial in healthy adults aged 18 years and older and elderly adults domestic; A randomized, double-blinded, placebo-controlled Phase II clinical trial in healthy adults aged 18 years and older and elderly adults domestic; A randomized, double-blinded, placebo-controlled, international multicenter Phase III clinical trial in population aged 18 years and older in Mexico, the Philippines, Indonesia and Kenya; A Phase II clinical trial on the safety and immunogenicity of booster vaccination in adults aged 18 years and older who have completed the primary series of 2 doses of COVID-19 vaccine for a minimum interval of 6 months overseas; and a clinical trial on the safety and immunogenicity of booster vaccination in adults aged 18 years and older who have completed 3 doses of inactivated COVID-19 vaccine for a minimum interval of 6 months initiated by the Chinese investigator. Adverse events were collected from the first dose to 28/30 days after the last dose in all subjects. Systematic safety follow-up was conducted from 0-7 days after each dose. Adverse events from Day 8 to the next dose or 28/30 days after the last dose were collected by subjects' voluntary reporting and investigators' regular follow-up. Attention is paid to the serious adverse events occurring from the first dose to 6/12 months after completion of the vaccination course.

1. General description of adverse reactions to this product in clinical trials

A total of 39,792 subjects were enrolled in the five clinical trials within and outside China, of which 19,647 subjects received at least one dose of the target amount (40 μg). Adverse reactions were classified according to the Frequency of Drug Adverse Reactions recommended by the Council for International Organization of Medical Sciences (CIOMS): very common (≥10%), common, (≥1% and <10%), uncommon, (≥0.1% and <1%), rare (≥0.01% and <0.1%), and very rare (<0.01%). Adverse reactions to this product were described as per the CIOMS criteria as follows:

(1) Injection site reactions:

Common: injection site pain, axillary swelling or tenderness, injection site redness, injection site swelling.

Very rare: injection site hematoma.

(2) Systemic reactions:

Common: headache, fatigue, fever, muscle pain, joint pain, nausea.

Uncommon: vomiting.

Rare: dizziness, pruritus, pain, hypersensitivity, malaise, migraine, rash, nasopharyngitis.

Very rare: dyspepsia, flatulence, dermatitis, cough, blepharospasm.

(3) Severity of adverse reactions:

Adverse reactions to this product observed in clinical trials were mainly grade 1 (mild) in severity. The incidence of grade 3 adverse reactions was 0.326%, the main symptoms were fever, fatigue, headache, injection site redness, muscle pain and nausea. There were no adverse reactions of grade 4 or above.

(4) Related serious adverse events (SAEs):

No serious adverse events related to vaccination with this product have been identified by investigators.

2. Adverse reactions to this product in clinical trials within and outside China

(1) Phase I/II clinical trials

A total of 1,128 subjects aged 18 years and older were enrolled in the Phase I/II clinical trials conducted domestic. In the vaccine group, 486 subjects (52.54%) were aged 18-59 years and 439 (47.46%) were aged 60 years and older. A total of 483 subjects were inoculated with the target dosage of 40 μg, including 259 subjects (53.62%) aged 18–59 years and 224 (46.38%) aged 60 years and older. By the time of data analysis, all subjects had finished safety follow-up 6/12 months after completion of the vaccination course.

Adverse reactions 28/30 days after inoculation with the target dosage of 40 μg were mainly solicited adverse reactions, and the overall incidence of adverse reactions was 24.22%, among which the incidence of adverse reactions in adults was 30.89%, and that in the elderly was 16.52%.

The majority of adverse reactions in the subjects were Grade 1 or Grade 2 in severity, and only 1 subject experienced Grade 3 local adverse reaction, i.e., injection site redness, the incidence rate of which was 0.11%. There were no systemic adverse reactions of Grade 3 or above.

Table 1 presents the safety data of Phase I/II clinical trials domestic.

Table 1 Adverse Reactions in Phase I/II Clinical Trials n (%)

Age group	18~59 years						≥60 years					
Vaccination Course	0, 21days		0, 28 days		0, 14, 28 days		0, 21days		0, 28 days		0, 14, 28 days	
Study group	WestVac COVID-19 vaccine (N=100) n (%)	Placebo (N=20) n (%)	WestVac COVID-19 vaccine (N=29) n (%)	Placebo (N=10) n (%)	WestVac COVID-19 vaccine (N=130) n (%)	Placebo (N=30) n (%)	WestVac COVID-19 vaccine (N=100) n (%)	Placebo (N=20) n (%)	WestVac COVID-19 vaccine (N=13) n (%)	Placebo (N=4) n (%)	WestVac COVID-19 vaccine (N=111) n (%)	Placebo (N=24) n (%)
Overall adverse reactions	24(24.00)	6(30.00)	10(34.48)	4(40.00)	46(35.38)	10(33.33)	14(14.00)	3(15.00)	3(23.08)	1(25.00)	20(18.02)	1(4.17)
Solicited adverse reactions	20(20.00)	5(25.00)	8(27.59)	4(40.00)	43(33.08)	10(33.33)	13(13.00)	2(10.00)	2(15.38)	1(25.00)	19(17.12)	1(4.17)
Local adverse reactions	17(17.00)	3(15.00)	3(10.34)	2(20.00)	36(27.69)	7(23.33)	9(9.00)	1(5.00)	2(15.38)	0	12(10.81)	1(4.17)
Injection site pain	16(16.00)	2(10.00)	2(6.90)	1(10.00)	26(20.00)	6(20.00)	9(9.00)	1(5.00)	1(7.69)	0	9(8.11)	1(4.17)
Injection site pruritus	1(1.00)	1(5.00)	0	1(10.00)	15(11.54)	0	1(1.00)	0	1(7.69)	0	4(3.60)	0
Injection site swelling	0	0	1(3.45)	0	4(3.08)	0	0	0	0	0	0	0
Injection site	0	0	0	0	4(3.08)	1(3.33)	0	0	0	0	0	0

redness												
Injection site induration	1(1.00)	0	0	0	3(2.31)	0	0	0	0	0	0	0
Systemic adverse reactions	7(7.00)	3(15.00)	6(20.69)	2(20.00)	15(11.54)	4(13.33)	5(5.00)	1(5.00)	1(7.69)	1(25.00)	12(10.81)	0
Cough	0	1(5.00)	3(10.34)	2(20.00)	3(2.31)	2(6.67)	1(1.00)	1(5.00)	0	0	2(1.80)	0
Fatigue	3(3.00)	0	3(10.34)	0	3(2.31)	0	1(1.00)	0	0	1(25.00)	2(1.80)	0
Fever	2(2.00)	0	1(3.45)	0	4(3.08)	0	1(1.00)	0	1(7.69)	0	3(2.70)	0
Headache	2(2.00)	0	0	0	4(3.08)	1(3.33)	1(1.00)	0	0	0	3(2.70)	0
Oropharyngeal pain	0	1(5.00)	1(3.45)	0	6(4.62)	0	1(1.00)	0	0	0	2(1.80)	0
Nausea	4(4.00)	0	0	0	3(2.31)	1(3.33)	0	0	0	0	1(0.90)	0
Joint pain	0	1(5.00)	0	0	2(1.54)	0	0	0	0	0	2(1.80)	0
Loss of appetite	0	0	0	0	1(0.77)	0	0	0	0	0	0	0
Unsolicited adverse reactions	6(6.00)	2(10.00)	4(13.79)	0	8(6.15)	0	1(1.00)	1(5.00)	1(7.69)	1(25.00)	1(0.90)	0

(2) Phase III clinical trial

A total of 38,390 subjects aged 18 years and older were enrolled in the Phase III clinical trial, and a total of 19,024 subjects were vaccinated with this product, 422 of which were aged 60 years and above. The overall incidence of adverse reactions to this product was 17.699%, the majority of which were Grade 1 and Grade 2 in severity, and the incidence of Grade 3 adverse reactions was 0.326%. The incidence of unsolicited adverse reactions was 0.315%, the symptoms included dizziness (0.058%), pruritus (0.026%), and pain (0.016%). Table 2 presents the solicited adverse reactions:

Table 2 Solicited adverse Reactions in Phase III Clinical Trial n (%)

Age group	18~59 years		≥60 years		18 years and above	
Adverse Reactions	WestVac COVID-19 vaccine (N=18602) n%	Placebo (N=18582) n%	WestVac COVID-19 vaccine (N=422) n%	Placebo (N=432) n%	WestVac COVID-19 vaccine (N=19024) n%	Placebo (N=19014) n%
Local adverse reactions	1790(10.88)	1541(9.38)	26(6.86)	16(4.15)	1816(10.79)	1557(9.26)
Injection site pain	1598(9.71)	1376(8.37)	20(5.28)	14(3.63)	1618(9.61)	1390(8.26)
Grade 1 & 2	1597(9.71)	1374(8.36)	20(5.28)	14(3.63)	1617(9.61)	1388(8.25)
≥ Grade 3	1(<0.01)	2(0.01)	0	0	1(<0.01)	2(0.01)
Injection site redness	235(1.43)	157(0.96)	6(1.58)	1(0.26)	241(1.43)	158(0.94)
Grade 1 & 2	231(1.40)	156(0.95)	6(1.58)	1(0.26)	237(1.41)	157(0.93)
≥ Grade 3	4(0.02)	1(<0.01)	0	0	4(0.02)	1(<0.01)
Injection site swelling	229(1.39)	159(0.97)	5(1.32)	1(0.26)	234(1.39)	160(0.95)
Grade 1 & 2	226(1.37)	159(0.97)	5(1.32)	1(0.26)	231(1.37)	160(0.95)
≥ Grade 3	3(0.02)	0	0	0	3(0.02)	0
Axillary swelling or tenderness	581(3.53)	478(2.91)	7(1.85)	5(1.30)	588(3.49)	483(2.87)
Grade 1 & 2	581(3.53)	478(2.91)	7(1.85)	5(1.30)	588(3.49)	483(2.87)
≥ Grade 3	0	0	0	0	0	0
Systemic adverse reactions	2384(14.49)	2247(13.67)	36(9.50)	40(10.36)	2420(14.38)	2287(13.60)
fever	914(5.60)	871(5.35)	14(3.69)	12(3.15)	928(5.55)	883(5.30)
Grade 1 & 2	873(5.35)	814(5.00)	14(3.69)	12(3.15)	887(5.31)	826(4.95)
≥ Grade 3	41(0.25)	57(0.35)	0	0	41(0.25)	57(0.34)
Headache	1062(6.45)	986(6.00)	18(4.75)	13(3.37)	1080(6.42)	999(5.94)
Grade 1 & 2	1057(6.42)	984(5.99)	18(4.75)	13(3.37)	1075(6.39)	997(5.93)

≥ Grade 3	5(0.03)	2(0.01)	0	0	5(0.03)	2(0.01)
Fatigue	1041(6.33)	967(5.88)	11(2.90)	13(3.37)	1052(6.25)	980(5.83)
Grade 1 & 2	1033(6.28)	964(5.87)	11(2.90)	13(3.37)	1044(6.20)	977(5.81)
≥ Grade 3	8(0.05)	3(0.02)	0	0	8(0.05)	3(0.02)
Nausea	327(1.99)	311(1.89)	4(1.06)	2(0.52)	331(1.97)	313(1.86)
Grade 1 & 2	326(1.98)	311(1.89)	3(0.79)	2(0.52)	329(1.95)	313(1.86)
≥ Grade 3	1(<0.01)	0	1(0.26)	0	2(0.01)	0
Vomiting	81(0.49)	76(0.46)	3(0.79)	2(0.52)	84(0.50)	78(0.46)
Grade 1 & 2	81(0.49)	76(0.46)	3(0.79)	2(0.52)	84(0.50)	78(0.46)
≥ Grade 3	0	0	0	0	0	0
Muscle pain	709(4.31)	662(4.03)	12(3.17)	15(3.89)	721(4.28)	677(4.02)
Grade 1 & 2	706(4.29)	660(4.02)	12(3.17)	15(3.89)	718(4.27)	675(4.01)
≥ Grade 3	3(0.02)	2(0.01)	0	0	3(0.02)	2(0.01)
Joint pain	389(2.36)	334(2.03)	9(2.37)	6(1.55)	398(2.36)	340(2.02)
Grade 1 & 2	388(2.36)	332(2.02)	9(2.37)	6(1.55)	397(2.36)	338(2.01)
≥ Grade 3	1(<0.01)	2(0.01)	0	0	1(<0.01)	2(0.01)

(3) Clinical trial on booster vaccination overseas

For “the observer-blind, randomized, controlled Phase II clinical trial to evaluate the safety and immunogenicity of booster vaccination of the Recombinant COVID-19 Vaccine (Sf9 cell) in adults aged 18 years and older who have completed the primary series of 2 doses of COVID-19 vaccine for a minimum interval of 6 months” conducted overseas, the enrollment of 150 subjects aged 18 years and older in the inactivated vaccine cohort as well as the safety observation 28 days after vaccination have been concluded. 75 out of the 150 subjects received a booster dose of this product. The overall incidence of adverse reactions to sequential booster vaccination of this product was 4.00%, all of which were Grade 1 in severity. The incidence of solicited adverse reactions was 2.67%, the symptoms included fatigue (1.33%), fever (1.33%). The incidence of unsolicited adverse reactions was 1.33%, the symptom of which was oropharyngeal pain (1.33%).

(4) Clinical trial on booster vaccination domestic

For “the clinical trial on the safety and immunogenicity of booster vaccination in adults aged 18 years and older who have completed 3 doses of inactivated COVID-19 vaccine for a minimum interval of 6 months” initiated by the Chinese investigator, 124 subjects aged 18 and older were enrolled, all of whom have completed the safety observation 7 days after vaccination. 65 out of the 124 subjects received this product in sequential booster vaccination. The overall incidence of adverse reactions to sequential booster vaccination of this product was 12.31%, all of which were Grade 1 in severity. The incidence of solicited adverse reactions was 12.31%, the symptoms included injection site pain (12.31%), injection site induration (1.54%).

[CONTRAINDICATIONS]

1. Anyone with an allergic reaction to the active ingredient, any inactive ingredient, or substances used in the manufacturing process of this product, or anyone who have developed an allergic reaction to vaccines of the same kind.
2. Anyone with previous severe allergic reactions to any vaccine (e.g., acute anaphylaxis, angioneurotic edema, dyspnea, etc.).
3. Patients with severe neurological disorders (e.g., transverse myelitis, Guillain-Barre Syndrome, demyelination disease, etc.).
4. Pregnant and breastfeeding women.

[WARNINGS AND PRECAUTIONS]

1. Check the packaging container, label, appearance and expiry date before use. Do not use it in case of any abnormal condition, such as crack in the glass vial, spot, stain, scratch on the outer surface, unclear label, expired product, or turbid product. Shake well before injection. Do not use it when there are coagulation or foreign matters that cannot be dispersed by shaking.
2. Do not freeze. Use immediately after opening.
3. Keep out of the reach of children.
4. Do not mix with other vaccine in the same syringe.
5. Do not use this product in intravascular injection. There are no data available on the safety and efficacy of this product in subcutaneous or intradermal injection.
6. Individuals should be observed for at least 30 minutes on site after vaccination. Medication such as epinephrine (adrenaline) and necessary equipment should be available on site for emergency treatment in event of a severe allergy.
7. A second dose should not be given to those who have experienced allergic reactions or other abnormal circumstances after the first dose.
8. Caution is advised in patients with diabetes or anyone with family or personal history of convulsion, epilepsy, encephalopathy, or psychiatric diseases.
9. Caution is advised in patients with acute diseases, allergy constitution and fever. When necessary, postpone the vaccination after health assessment.
10. Caution is advised in patients with thrombocytopenia and coagulation disorders where intramuscular injection of this product may cause bleeding.
11. This product should be given at least one month after injection of immunoglobulin to avoid compromising the efficacy of this product.
12. There are no data available on the safety and efficacy of this product on immunocompromised individuals (such as patients with malignant tumor, nephrotic syndrome and HIV/AIDS). Vaccination in this population should

be based on individual considerations.

13. The duration of protection has not yet been established. Necessary protective measures should be taken after vaccination according to the needs of pandemic prevention and control.
14. There is no evidence on the efficacy of this product on individuals infected with SARS-CoV-2 or with a history of infection.
15. As with any vaccine, vaccination with this product may not protect all vaccine recipients.

[DRUG INTERACTIONS]

1. Concomitant use with other vaccines: Based on the clinical trial results on sequential booster within and outside China, one sequential booster dose of this product in adults aged 18 and older who have completed 2/3 doses of COVID-19 vaccine for a minimum interval of 6 months, information on safety refers to **[ADVERSE REACTIONS]**, increases the level of the SARS-CoV-2 euvirus neutralizing antibodies significantly. No clinical studies have been conducted on the effect of concomitant or subsequent administration of other vaccines on the immunogenicity of this product.
2. Concomitant use with other drugs: Drugs with immunosuppressive effects, such as immunosuppressive therapy, chemotherapy, antimetabolites, alkylating agents, cytotoxic therapy, corticosteroids, etc., may compromise the immune response to this product.
3. Patients undergoing treatment: For those who are on medication, it is recommended to consult medical professionals before administering this product to avoid potential drug interactions.

[SPECIAL POPULATIONS]

1. Women of childbearing age: Limited data are available in clinical studies in women with unintended pregnancy following vaccination with this product, which is not enough to determine the risks of adverse pregnancy outcomes after vaccination.
2. Pregnancy and lactating women: There are no clinical data available on the use of this product in pregnant and breastfeeding women.
3. People aged 60 years and above: Limited data are available in clinical studies conducted within and outside China on the safety and efficacy of this product in the elderly population aged 60 years and above.
4. Pediatric population: the safety and efficacy of this product in children have not yet been established.
5. People with underlying conditions: At present, limited data are available on the safety and efficacy of this product in patients with obesity, diabetes, chronic lung diseases, and cardiovascular diseases.

【Drug overdose 】

This product is packaged in individual dose. This section is not applicable.

[CLINICAL TRIALS]

1. Clinical results on efficacy

The pivotal Phase III clinical trial was designed as a randomized, double-blinded, placebo-controlled, international multicenter clinical trial in the healthy population aged 18 years and above in Mexico, the Philippines, Indonesia and Kenya, etc. to evaluate the efficacy of this product.

The primary efficacy endpoint is the efficacy of this recombinant COVID-19 vaccine (Sf9 cell) in preventing virologically confirmed (PCR positive) symptomatic COVID-19 cases 28 days after 3 doses of vaccination, regardless of severity. By the time of this analysis, a total of 20,478 subjects had been enrolled in the Phase III clinical study overseas on the efficacy of this product, with a total of 178 valid cases obtained for the primary endpoint, including 40 cases in the vaccine group and 138 in the placebo group. The primary efficacy of this product in preventing virologically confirmed (PCR positive) symptomatic COVID-19 in the population aged 18 years and above (overall population) 28 days after 3 doses of vaccination regardless of severity was 70.95% (95% CI: 58.69%, 79.57%), as detailed in Table 3.

A total of 249 valid cases were obtained for the secondary endpoint in this analysis, including 52 in the vaccine group and 197 in the placebo group. The secondary efficacy of this product in preventing the first occurrence of virologically confirmed (PCR positive) symptomatic COVID-19 in the population aged 18 years and above (overall population) 14 days after 3 doses of vaccination regardless of severity was 73.54% (95% CI: 64.08%, 80.51%), as detailed in Table 4. The efficacy in preventing the first occurrence of virologically confirmed (PCR positive) moderate, hospitalized severe COVID-19 and deaths from SARS-CoV-2 infection 14 and 28 days after 3 doses of vaccination were both 100% (95% CI: -, 100%), as detailed in Table 5 and Table 6.

Phase III clinical trial overseas indicated that the primary efficacy of this product in preventing virologically confirmed (PCR positive) symptomatic COVID-19 in the elderly population (60 years and older) 28 days after 3 doses of vaccination regardless of severity was 78.97%; the secondary efficacy in preventing virologically confirmed (PCR positive) symptomatic COVID-19 14 days after 3 doses of vaccination regardless of severity was 85.06%.

Based on the gene sequencing of endpoint cases in Phase III clinical trial: the SARS-CoV-2 Omicron variant accounted for 97.33% of all the sequenced cases, indicating good efficacy of this product against COVID-19 caused by SARS-CoV-2 Omicron variant.

Table 3 Efficacy in Preventing the First Occurrence of Virologically Confirmed (PCR

Positive) Symptomatic COVID-19 from Day 28 after the 3rd Dose

Analysis set	Group	N (Subjects)	COVID-19 cases	VE (%)	95%LCL (%)	95%UCL (%)	P-value[1]
FAS3-D29[2]	Vaccine group	10248	40	70.95	58.69	79.57	<0.0001
	Placebo group	10230	138				
PPS-D29[3]	Vaccine group	10241	40	70.97	58.72	79.58	<0.0001
	Placebo group	10218	138				

Notes: Follow-up days were counted from the day of the first dose.

[1] Vaccine efficacy VE/30%.

[2] FAS3-D29 (Full Analysis Set 3-Day 29)：Inclusion of all subjects who received 3 doses with no experience of COVID-19 or censored data before Day 29 after the 3rd dose of vaccine, regardless of their protocol compliance and continuation of participation in the study.

[3] PPS-D29 (Per Protocol Set –Day 29)：Inclusion of all subjects who received 3 group-consistent doses of vaccine or placebo with no major protocol deviations affecting the efficacy evaluation and no experience of COVID-19 or censored data before Day 29 after the 3rd dose of vaccine.

Table 4 Efficacy in Preventing the First Occurrence of Virologically Confirmed (PCR Positive) Symptomatic COVID-19 from Day 14 after the 3rd Dose

Analysis set	Group	N (Subjects)	COVID-19 cases	VE (%)	95% LCL (%)	95% UCL(%)	P-value[1]
FAS3-D15[2]	Vaccine group	12325	52	73.54	64.08	80.51	<0.0001
	Placebo group	12383	197				
PPS-D15[3]	Vaccine group	12316	52	73.57	64.12	80.53	<0.0001
	Placebo group	12367	197				

Notes: Follow-up days were counted from the day of the first dose.

[1] Vaccine efficacy VE/30%.

[2] FAS3-D15 (Full Analysis Set 3-Day 15)：Inclusion of all subjects who received 3 doses with no experience of COVID-19 or censored data before Day 15 after the 3rd dose of vaccine, regardless of their protocol compliance and continuation of participation in the study.

[3] PPS-D15 (Per Protocol Set –Day 15)：Inclusion of all subjects who received 3 group-consistent doses of vaccine or placebo with no major protocol deviations affecting the efficacy evaluation and no experience of COVID-19 or censored data before Day 15 after the 3rd dose of vaccine.

Table 5 Efficacy in Preventing the First Occurrence of Virologically Confirmed (PCR Positive) Moderate, Hospitalized Severe COVID-19 and Deaths from SARS-CoV-2

Infection from Day 28 after the 3rd Dose

Analysis set	Group	N (Subjects)	COVID-19 cases	VE (%)	95% LCL (%)	95% UCL (%)	P-value[1]
FAS3-D29[2]	Vaccine group	10248	0	100.00	-	100.00	0.4978
	Placebo group	10230	3				
PPS-D29[3]	Vaccine group	10241	0	100.00	-	100.00	0.4978
	Placebo group	10218	3				

Notes: Follow-up days were counted from the day of the first dose.

[1] Vaccine efficacy VE/30%.

[2] FAS3-D29 (Full Analysis Set 3-Day 29)：Inclusion of all subjects who received 3 doses with no experience of COVID-19 or censored data before Day 29 after the 3rd dose of vaccine, regardless of their protocol compliance and continuation of participation in the study.

[3] PPS-D29 (Per Protocol Set –Day 29)：Inclusion of all subjects who received 3 group-consistent doses of vaccine or placebo with no major protocol deviations affecting the efficacy evaluation and no experience of COVID-19 or censored data before Day 29 after the 3rd dose of vaccine.

Table 6 Efficacy in Preventing the First Occurrence of Virologically Confirmed (PCR Positive) Moderate, Hospitalized Severe COVID-19 and Deaths from SARS-CoV-2 Infection from Day 14 after the 3rd Dose

Analysis set	Group	N (Subjects)	COVID-19 cases	VE (%)	95% LCL (%)	95% UCL (%)	P-value[1]
FAS3-D15[2]	Vaccine group	12325	0	100.00	-	100.00	0.4976
	Placebo group	12383	4				
PPS-D15[3]	Vaccine group	12316	0	100.00	-	100.00	0.4976
	Placebo group	12367	4				

Notes: Follow-up days were counted from the day of the first dose.

[1] Vaccine efficacy VE/30%.

[2] FAS3-D15 (Full Analysis Set 3-Day 15)：Inclusion of all subjects who received 3 doses with no experience of COVID-19 or censored data before Day 15 after the 3rd dose of vaccine, regardless of their protocol compliance and continuation of participation in the study.

[3] PPS-D15 (Per Protocol Set –Day 15)：Inclusion of all subjects who received 3 group-consistent doses of vaccine or placebo with no major protocol deviations affecting the efficacy evaluation and no experience of COVID-19 or censored data before Day 15 after the 3rd dose of vaccine.

2. Immunogenicity

(1) Humoral immunity

The immunogenicity of this vaccine has been analyzed in Per Protocol Set (PPS) based on the Phase Ⅰ and Phase Ⅱ clinical trials of this product performed in the population aged 18 years and older domestic, the international multicenter Phase III clinical trial, and the clinical trials on booster vaccination within and outside China. The indicator for immunogenicity is the difference between serum antibody titers before and after vaccination in subjects, including geometric mean titer (GMT), geometric mean increase (GMI), and the positive seroconversion rate of the SARS-CoV-2 euvirus neutralizing antibodies. The SARS-CoV-2-specific neutralizing antibodies were determined by a micro-dose cytopathogenic efficiency (CPE) assay.

Phase I and Phase II clinical trials domestic: a single dose of this vaccine induced the body to produce SARS-CoV-2 euvirus neutralizing antibodies, which peaked in serum one month after 3 doses of vaccination, the seroconversion rates of the SARS-CoV-2 euvirus neutralizing antibodies was 100% in adult subjects and 77% in elderly subjects. The long-term immunogenicity data showed that the SARS-CoV-2-specific neutralizing antibodies remained at 70.99% of the peak level 3 months after 3 doses of vaccination and 51.74% of the peak level 6 months after 3 doses, indicating that this product was of good immune persistence.

The international multicenter Phase III clinical trial: 28 days after 3 doses of vaccination, calibrated with the WHO international standard for anti-SARS-CoV-2 immunoglobulin (NIBSC 20/136), the SARS-CoV-2-specific neutralizing antibodies in the serum of subjects of the vaccine group showed a geometric mean titer (GMT) of 2089.39IU/mL, a geometric mean increase (GMI) of 24.71, and a positive seroconversion rate of 91.30%.

The clinical trial on booster vaccination overseas: 1 booster dose of this product to the healthy population who had completed the primary series of 2 doses of inactivated COVID-19 vaccine for a minimum interval of 6 months induced the subjects to produce relatively high level of specific neutralizing antibodies against both the SARS-CoV-2 wild-type and the Omicron variant. 14 days after vaccination, the geometric mean increase (GMI) of the neutralizing antibodies in the serum of subjects in the Coviccine group against Omicron BA.1 and BA.5 was over 10 times.

The clinical trial on booster vaccination domestic: 1 booster dose of this product to the healthy population who had completed the primary series of 3 doses of inactivated COVID-19 vaccine for a minimum of 6 months induced the subjects to produce relatively high level of specific neutralizing antibodies against both the SARS-CoV-2 wild-type and the Omicron variant. After the

booster vaccination, the neutralizing antibodies in the serum of subjects in the Coviccine group against Omicron BA.1, BA.2, BA.4 and BA.5 increased by 50 times or above.

(2) Cellular immunity
One booster dose of this product in booster vaccination induced specific T-cell immunity. 14 days after vaccination, ELISPOT showed that IFN-γ-positive T-cells reached 91.93%

[STORAGE]

Store and transport between 2℃ and 8℃, and protect from light. Do not freeze.

Product that is frozen shall not be administered.

[PACKAGE]
Packed in injection vials made of middle borosilicate glass tubing, and covered with a bromobutyl rubber stopper for injection which does not contain natural latex.1.0 mL/vial, 1 vial/box,10 vials/box.

[SHELF-LIFE]
24 months tentatively.

[EXECUTIVE STANDARD]
Manufacturing and Verification Procedures for Recombinant COVID-19 Vaccine (Sf9 cell).

[AUTHORIZATION NUMBER]
To be determined. National authorization, for emergency use.

[MARKETING AUTHORIZATION HOLDER]
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