Pharmaniaga LifeScience Sdn Bhd (198201002939 (82685-T))
Lot 7, Jalan PPU 3,
Taman Perindustrian Puchong Utama,
47100 Puchong,
Selangor, Malaysia.

19 December 2023

Direct Healthcare Professional Communication:

CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell, Inactivated) [MAL21036010ARZ]

Product Label Notice

Dear Healthcare Professional,

Please be informed that details in the vial label (immediate label) and outer carton label for CoronaVac are based on the global product information issued by the manufacturer, Sinovac Life Sciences Co., Ltd., P.R China.

However, product details specified in the Package Insert (PI) and Patient Information Leaflet (PIL) are based on information approved by Drug Control Authority (DCA), Malaysia. As such, there are differences of information in the product vial label, outer carton label, PI, PIL as follows:

Details	Global Label (Sinovac Life Sciences Co., Ltd., China) (Vial and outer carton)		Local Label Approved by DCA, Malaysia (PI and PIL)
	Single-dose (1 dose) vial of 0.5 mL	Multi-dose (2 doses) vial of 1.0 mL	
Product Name	CoronaVac COVID-19 Vaccine (Vero Cell), Inactivated	CoronaVac® COVID-19 Vaccine (Vero Cell), Inactivated	CoronaVac Suspension for Injection, COVID-19 Vaccine (Vero Cell), Inactivated
Indication	This vaccine is indicated in population aged 18 years and over. COVID-19 Vaccine (Vero Cell), Inactivated can stimulate body to induce immunity against the disease caused by SARS-CoV-2 virus.	Susceptible people aged 18 and above. CoronaVac® is indicated for active immunization against diseases caused by SARS-CoV-2 virus.	CoronaVac is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2, in individuals 5 years of age and older. The use of this vaccine should be in accordance with official recommendations.

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Details	Global Label (Sinovac Life Sciences Co., Ltd., China) (Vial and outer carton)		Local Label Approved by DCA, Malaysia (PI and PIL)
	Single-dose (1 dose) vial of 0.5 mL	Multi-dose (2 doses) vial of 1.0 mL	
Dose	The immunization schedule is 2 doses at 2-week interval	Two doses should be administered for primary immunization. The second dose is preferably given 14 – 28 days after the first dose. 0.5 mL per dose	Individuals 18 years of age and older Two doses should be administered for primary immunization. The second dose is preferably given 14 - 28 days after the first dose. 0.5 mL per dose. A booster dose (0.5mL) may be administered at least 3-6 months after the second dose when the potential benefits outweigh any potential risks. The decision when and for whom to implement a booster dose of the vaccine should be made based on available vaccine effectiveness data, taking into account limited safety data (see clinical data). Children and adolescent 5 years to 17 years of age Two doses should be administered for primary immunization. The second dose is preferably given 28 days after the first dose. 0.5 mL per dose. Elderly population No dosage adjustment is required in elderly individuals ≥ 60 years of age. There is limited data on the use of CoronaVac in individuals ≥ 60 years of age. CoronaVac, when administered to individuals ≥ 60 years of age, has shown adequate and similar neutralizing antibodies titres as in

Details	Global Label (Sinovac Life Sciences Co., Ltd., China) (Vial and outer carton)		Local Label Approved by DCA, Malaysia (PI and PIL)
	Single-dose (1 dose) vial of 0.5 mL	Multi-dose (2 doses) vial of 1.0 mL	
			adults. At present, it is recommended that vaccination for people aged 60 and above should be considered cautiously and its necessity should be evaluated based on their health condition and exposure risk.
Shelf life (from date of manufacture)	36 months (by way of expiry date)	24 months	36 months

For the avoidance of doubt, all healthcare professionals are advised to refer **ONLY** to the information in the product PI, and PIL, which is specific for use of CoronaVac in the Malaysian population.

Please take note that the shelf life approved by DCA, Malaysia for CoronaVac is 36 MONTHS. Therefore, upon receipt of CoronaVac supply, healthcare professionals are advised to transcribe the actual expiry date onto the vial label. The actual expiry date is calculated as a period of 36 MONTHS (approved shelf life) from the product manufacturing date. The product manufacturing date can be found on the outer carton label.

The communication of this information has been agreed with the National Centre for National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health Malaysia.

Call for Adverse Event Following Immunisation (AEFI) reporting

To make a report, kindly contact the National Centre for Adverse Drug Reaction Monitoring, National Pharmaceutical Regulatory Agency (NPRA):

- By phone: 03-78835400 (Ext: 5450/5448)
- By facsimile: 03-79567075 using the form available at: https://npra.gov.my/index.php/en/health-professionals/reporting-adr.html

  Or mail to the following address:

  National Pharmaceutical Regulatory Agency (NPRA)
  Lot 36, Jalan Universiti (Jalan Profesor Diraja Ungku Aziz)
  46200 Petaling Jaya
  Selangor, Malaysia

All AEFI encountered with the use of CoronaVac should also be reported to Pharmaniaga LifeScience Sdn. Bhd., Nurul Fazila Binti Faidzul Adzhar (RPPV) at +603-33429999 ext 692 or email to drugsafetyunit@pharmaniaga.com.

Thank you.

Yours sincerely,

Intan Soleha Binti Hj. Ahmad Pudelani
Responsible Person for Pharmacovigilance.
Pharmaniaga LifeScience Sdn Bhd.

克尔来福 CoronaVac
Suspension for Injection

SINOVAC pharmaniaga

CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated

CONTROLLED MEDICINE / UBAT TERKAWAL

DISCLAIMER: THIS PRODUCT IS APPROVED UNDER MALAYSIAN CONDITIONAL REGISTRATION FOR PHARMACEUTICAL PRODUCTS DURING DISASTER GUIDELINE. THE ADMINISTRATION OF THE PRODUCT IS PURELY BASED ON INDIVIDUAL'S PREFERENCE.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions.

This product information will be updated on a regular basis as further data and safety reports become available.

The information stated on inner and outer carton labels is based on the global label. For Malaysia specific information, please refer this package insert.

COMPOSITION
Each dose (0.5 mL) contains 600 SU (equivalent to 3μg) of inactivated SARS-CoV-2 antigen.
Excipient: Aluminium hydroxide, disodium hydrogen phosphate, monosodium dihydrogen phosphate, sodium chloride and water for injection. There is no preservative in this product.

DESCRIPTION
CoronaVac is a milky-white (opalescent) suspension. Stratified precipitate may form which can be dispersed by shaking.

CoronaVac is available in the following presentations:
- Single-dose (1 dose) vial of 0.5 mL
- Multi-dose (2 doses) vial of 1.0 mL

INDICATION
CoronaVac is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 5 years of age and older.

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

RECOMMENDED DOSAGE
Individuals 18 years of age and older
Two doses should be administered for primary immunization. The second dose is preferably given 14 - 28 days after the first dose. 0.5 mL per dose.

A booster dose (0.5ml) may be administered at least 3-6 months after the second dose when the potential benefits outweigh any potential risks.

The decision when and for whom to implement a booster dose of the vaccine should be made based on available vaccine effectiveness data, taking into account limited safety data (see clinical data).

Children and adolescent 5 years to 17 years of age
Two doses should be administered for primary immunization. The second dose is preferably given 28 days after the first dose. 0.5 mL per dose.

Elderly population
No dosage adjustment is required in elderly individuals ≥ 60 years of age.

There is limited data on the use of CoronaVac in individuals ≥ 60 years of age. CoronaVac, when administered to individuals ≥ 60 years of age, has shown adequate and similar neutralizing antibodies titres as in adults. At present, it is recommended that vaccination for people aged 60 and above should be considered cautiously and its necessity should be evaluated based on their health condition and exposure risk.

Method of administration
CoronaVac should be administered by intramuscular injection in the deltoid region of the upper arm.

Instruction for use

Shake before use.

Inspect visually prior to administration.

The vaccine should not be used if foreign particles are present in the suspension.

Upright position tilted at 45° is recommended to withdraw 0.5 mL of each vaccine dose into a 1mL Low-Dead-Volume (LDV) syringe. The LDV syringe and needle combination should have a dead volume of no more than 0.05mL.

Use a separate sterile needle and syringe for each individual dose. Aseptic techniques should be used when withdrawing each dose of the vaccine.

Recommended needle sizes for vaccine withdrawal: 21G with the length size at least 38mm ($1\frac{1}{2}$").

Recommended needle size for vaccination: 25G / 25mm.

Vaccine should be administered immediately after withdrawal from the vial.

For multi-dose vials, precautions must be taken to avoid contamination of the vial content.

Any excess volume inside the vial after the first withdrawal to be extracted completely to ensure the amount of vaccine meet the 0.5 mL dose for the second injection.

If there is insufficient volume withdrawn, check if there is any more vaccine residual leftover in the vial at upright position for at least 30 seconds.

ROUTE OF ADMINISTRATION
Intramuscular injection.

CONTRAINDICATIONS
1. Individuals who are hypersensitive or known to be allergic to any component (active ingredients or excipients or any material used in process) of the vaccine or similar vaccines;
2. Previous severe allergic reactions to the vaccine (e.g., acute anaphylaxis, angioedema, dyspnea);
3. Individuals with severe neurological conditions (e.g., transverse myelitis, Guillain-Barré syndrome, demyelinating diseases.);
4. Individuals with uncontrolled severe chronic diseases.

WARNINGS AND PRECAUTIONS
1. There is limited data on the duration of protection afforded by the vaccine. As such, necessary protective measures should be taken in line with the COVID-19 epidemic.
2. This vaccine should under no circumstances be administered intravascularly. There are no safety or efficacy data for administration of CoronaVac via subcutaneous or intradermal routes.
3. As with all injectable vaccines, appropriate supervision and treatment including adrenaline injection and emergency care should always be readily available in case of an anaphylactic reaction following the administration of the vaccine. Individuals should be observed for at least 30 minutes on site after vaccination.
4. Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.
5. CoronaVac should be used with caution in individuals with acute diseases, acute exacerbation of chronic diseases, severe chronic diseases, allergies and fever. If necessary, vaccination should be delayed upon doctor's assessment.
6. CoronaVac should be used with caution in individuals with diabetes, convulsions, epilepsy, encephalopathy and mental illness or family history of mental illness.
7. Further use of CoronaVac should be avoided in individuals who experience adverse effects related to the nervous system following administration.
8. As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) as bleeding or bruising may occur following an intramuscular administration in these individuals.
9. The safety and efficacy, of the vaccine has not been assessed in those with impaired immune function (patients with malignant tumour, nephrotic syndrome, AIDS) including those receiving immunosuppressant therapy. Use of CoronaVac in these individuals should be in consideration of a potentially lowered immune response.
10. Human immunoglobulin injections should be given at least one-month interval before or after the administration of the vaccine to avoid lowered immune response.
11. Do not use if there are cracks, spots, stains and scratches on the outer surface of the glass vial or if label is not clear.
12. Do not mix CoronaVac with other vaccines in the same syringe.
13. Avoid exposure of CoronaVac to disinfectants during use.
14. Do not freeze. It shall be administered immediately after opening.
15. This product should be stored out of reach of children.

16. As with any vaccine, the protective effect of CoronaVac may not reach 100% for all recipients.
17. The safety and immunogenicity of a booster dose of CoronaVac in individuals 18 years of age and older is based on safety and immunogenicity data of phase I/II clinical trial in individuals 18 years of age and older.

INTERACTIONS WITH OTHER MEDICAMENTS
Concomitant administration of other vaccines: No interaction studies have been performed.
There are no clinical studies on the concomitant (pre, post or simultaneous) use of CoronaVac with other vaccines.

Immunosuppressive drugs: The use immunosuppressive drugs such as immunity inhibitors, chemotherapy drugs, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids may lower the immune response of CoronaVac. The use of CoronaVac in individuals receiving immunosuppressive treatments and/or drugs should be determined by a doctor.

Incompatibility
This vaccine should not be mixed with the other vaccines in the same syringe.

SPECIAL POPULATION MEDICATION
Pregnancy
Limited experience exists with use of CoronaVac in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. Administration of CoronaVac in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.

Breastfeeding
It is unknown whether CoronaVac is excreted in human milk.

Fertility
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

ADVERSE EFFECTS
The safety of CoronaVac was evaluated in 9 clinical trials conducted in China and other countries, including randomized, double-blind, placebo-controlled, phase I/II clinical trials in paediatric population (aged 3-17 years), in adult population (aged 18-59 years), in elderly (aged 60 years and above), phase II(b) clinical trial in paediatric population (aged 3-17 years), phase III clinical efficacy trial in Brazilian health professionals (aged 18 years and above), phase III clinical efficacy trial in Indonesia (adults aged 18-59 years), phase III clinical efficacy trial in Turkey (adults aged 18-59 years) and a phase III(b) bridging trial in different production scales and different populations and phase III clinical efficacy, immunogenicity and safety trial in South Africa, Chile, Malaysia and Philippines (study designed to include children and adolescents from 6 months to 17 years of age).

Local and systematic safety observation was carried out within 30 minutes and 7 days respectively, after each vaccination. Adverse events were collected by solicited and unsolicited reporting methods within 0-7 days and 0-28 days respectively, after each vaccination. Regular follow-up of investigators on 8-14/28 days, long-term of serious adverse events within 6/12 months after the full vaccination is still ongoing.

General description of adverse reactions in clinical trials of this product
Over 27,000 subjects aged 18 and above have completed 2nd dose of vaccination in a series of clinical trials conducted in China, Turkey, Indonesia and Brazil.

A total of 1,028 subjects aged 3 to 17 years old were enrolled in a series of clinical trials (Phase I/II and II(b)) conducted in China.

All subjects have completed at least 28 days follow-up after full immunization, and long-term safety visits are ongoing.

An ongoing Phase III clinical trial conducted in South Africa, Chile, Malaysia and Philippines has enrolled a total of 7,893 subjects aged 3 to 17 years as of 7 February 2022. This study will enroll 14,000 healthy children and adolescents aged from 6 months to 17 years old and case monitoring will continue until one year after the second vaccination.

The safety of CoronaVac booster dose was evaluated in 271 healthy adults aged 18-59 years old and 318 elderly population aged 60 years and above which based on phase I/II clinical trial to evaluate the safety and immunogenicity of COVID-19 vaccine.

Adverse event frequencies are based on the grading standard of adverse reaction incidence from Council for International Organizations of Medical Sciences (CIOMS): Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

All adverse reactions for both primary vaccination schedule and booster dose are summarized and described as follows.

Localised (Injection Site) adverse reactions
Very common: pain
Common: swelling, pruritus, erythema, induration
Uncommon: warmth

Systemic adverse reactions
Very common: headache, fatigue
Common: myalgia, nausea, diarrhoea, arthralgia, cough, chills, rhinorrhoea, nasal congestion, sore throat, abdominal pain, decreased appetite, pruritus
Uncommon: vomiting, hypersensitivity, tremors, flushing, dizziness, drowsiness, mucocutaneous rash, fever, oedema
Rare: muscle spasms, abdominal distension, constipation, nose bleed/ epistaxis, hot flushes, ocular congestion, periorbital oedema, hyposmia

OVERDOSE AND TREATMENT
In the Phase I/II clinical trials, 286 adults and 245 elderly subjects were administered with high dosage of CoronaVac (1200SU/dose/0.5mL). There were no significant differences in the overall adverse reaction observed between adults and elderly. Most of the adverse reactions were mild and moderate, indicating that the safety of high dosage of CoronaVac is acceptable.

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE
CoronaVac 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.

PHARMACODYNAMICS
Mechanism of Action
CoronaVac has been developed by inactivating SARS-CoV-2 coronavirus, isolated from COVID-19 infected patients in China. The virus seed was cultured in large-scale Vero cells factories, and inactivated so that it is unable to replicate in vivo while still maintaining the structural integrity of virus particles. The purified viruses were mixed with Al $(OH)_3$ adjuvant and served as SARS-CoV-2 vaccine. Viral structural proteins, including spike protein (S- protein) can activate the immune system and produce neutralizing antibodies which may contribute to protection against COVID-19 infection.

Immunogenicity
In Phase I/II study in healthy adults, safety, tolerability and immunogenicity of 3μg / 0.5 ml and 6μg / 0.5 ml dose was evaluated at different dosing schedules. Studies demonstrated 92% seroconversion for neutralizing antibody titres in 2-dose vaccination schedule at 0, 14 days with 3μg / 0.5 ml, which was comparable to high dose of 6μg / 0.5 ml. In addition, the study demonstrated 97% seroconversion for neutralizing antibody titre for 3μg / 0.5 ml dose administered at 0, 28-day schedule. Following 2 doses of vaccination, all the enrolled participants received a booster dose after 6 months. The seroconversion rates and Geometric Mean Titres (GMT) after 28 days vaccination showed 95.92% and 143.1% respectively. The immunogenicity response in adults vaccinated with booster dose according to the 0,14-days and 0,28-day schedule is non-inferior to adult vaccinated with primary immunization.

Immunization schedule (days)	**0,14 schedule**	**0,28 schedule**
Index	GMT (95%CI)	GMT (95%CI)
Primary dose	27.61 (22.72,33.54)	44.07 (37.16,52.25)
Booster dose	137.91 (99.90,190.37)	143.07 (110.81,184.73)
Rate Difference (%)/GMT Ratio	4.99 (3.49,7.15)	3.25 (2.38,4.42)

Table 1 Immunogenicity results in phase Ⅱ clinical trial in adults 18-59 years old

In another Phase I/II study in elderly population of age 60 years and above, safety and immunogenicity of vaccine is evaluated in 0, 28-day schedule. The seroconversion rates (≥ 1:8) in 3μg / 0.5 ml and 6μg / 0.5 ml dose arm were 97.96% and 98.98% respectively. Following 2 doses of vaccination, all the enrolled participants received a booster dose after 6 months. The seroconversion rates and GMT after 28 days vaccination showed 98.84% and 342.8% respectively. The immunogenicity response in elderly vaccinated with booster dose according to

the 0,28-day schedule is non-inferior to elderly vaccinated with primary immunization.

Study phase	Ⅰ		Ⅱ	
Index	Sero-positive rate (%)	GMT (95%CI)	Sero-positive rate (%)	GMT (95%CI)
Primary dose	100.00	54.92 (38.58, 78.17)	97.96	42.19 (35.18, 50.61)
Booster dose	100.00	237.61 (134.47, 419.86)	98.84	342.81 (266.42, 441.09)
Rate Difference (%)/GMT Ratio	0.00 (-0.16, 0.14)	4.33 (2.31, 8.10)	0.88 (-4.46, 6.14)	8.12 (6.00, 11.01)

Table 2 Immunogenicity results in phase Ⅰ/Ⅱ clinical trial in elderly aged 60 years and above

In Phase I/II study in paediatric population of age 3-17 years of age, safety and immunogenicity of vaccine is evaluated in 0, 28-day schedule. The immunogenicity results showed that on 28th days after the second dose, seroconversion rates were higher than 96% in both 1.5μg / 0.5 ml and 3μg / 0.5 ml dose arm. The GMT in 3μg / 0.5 ml and 1.5μg / 0.5 ml dose arm were 142.2 and 86.4 respectively showed that GMT in 3μg / 0.5 ml dose arm was higher than that in 1.5μg / 0.5 ml dose arm. The results suggest the immunogenicity induced by two doses of medium dose (3μg / 0.5 ml dose arm) CoronaVac was favourable in individuals aged 3-17 years.

In Phase III study conducted in Indonesia, the immune response for seropositive rate of COVID-19 antibody using ELISA assay at 14 days, 3 months, and 6 months after second injection were 99.74%, 99.23%, and 84.87% respectively. Seroconversion rate 14 days after second injection were 97.48%. While the IgG antibody GMT before injection, 14 days, 3 months, and 6 months after second injection were 220.27, 5181.19, 1605.90, and 670.12, respectively.

The immune response for seropositive rate of COVID-19 neutralizing antibody using neutralization assay in the vaccine group at 14 days, 3 months and 6 months after second injection were 95.72%, 83.85%, and 44.10%. Seroconversion rate 14 days after second injection were 87.15%. The GMT before injection, 14 days, 3 months, and 6 months after second injection were 2.00, 15.76, 7.12, and 5.08, respectively.

In Phase III study in Chile for paediatric population of age 3-17 years of age, safety, efficacy and immunogenicity of vaccine is evaluated in 0, 28-day schedule. The preliminary immunogenicity results as of December 2021 showed that 28th days after the second dose, the geometric mean titers (GMT) were 68.16, 74.66 and 256.0 for the 12-17, 6-11 and 3-5 years groups, respectively. Seropositivity rate 4 weeks after second dose was 100% in all age groups. Seroconversion rates 4 weeks after second dose were 100% in 3-5 and 6-11 years old and 96.7% in 12-17 years old.

Immune-bridging on neutralizing antibody comparison was conducted to compare the seropositive rate and GMT response of vaccinated subjects in the paediatric, adult and elderly populations using minimum cut-off non-inferior margin of (-)10% for seropositive rate and a GMT ratio (GMR) margin of 0.67. Neutralizing antibodies level, after completion of 2-dose vaccination, is identified as suitable biomarkers to infer COVID-19 vaccine effectiveness from adults to paediatric populations via immunobridging. Serum samples were obtained from Phase I/II clinical trials in the elderly, Phase I/II clinical trials in children and adolescents aged 3-17 years old and Phase III(b) clinical trials in adults.

The results of the study shows that the immunogenicity response of adolescents and children vaccinated according to the 0,28-day schedule is superior to immunogenicity response in adults who were vaccinated with 0,14-day schedule. The immunogenicity response in elderly vaccinated according to the 0,28-day schedule is non-inferior to that of adults vaccinated according to the 0,14-day schedule. The study successfully demonstrated that CoronaVac produces comparable immune response in children, adolescents and elderly according to 0,28-day schedule to that of adults.

Efficacy
A Phase III, multicentre, randomised clinical study in high-risk health care population in Brazil, two-doses vaccination of CoronaVac at 0,14-day schedule was studied. Results showed in the primary efficacy analysis that the efficacy of the vaccine was 50.65% (95.38%CI: 35.66, 62.15) according to the case definition recommended by National Medical Products Administration (NMPA), achieved the WHO recommended validity criteria that protective effect ≥50% and lower limit of 95% CI ≥30%. The efficacy results against cases with different severity showed favourable protective effect on moderate and severe cases: the efficacy against cases scored ≥3 achieved 83.70% (95%CI: 57.99, 93.67); the efficacy against cases scored ≥4 and severe cases achieved 100%.

A randomized, double-blind, placebo-controlled Phase III clinical trial to evaluate the efficacy and safety at 0,14-day schedule was conducted in Turkey. Outcome in the primary efficacy analysis showed that vaccine efficacy was 91.90% (95%CI 76.95-97.93) against the symptomatic COVID-19 cases determined based on the case definition recommended by NMPA, achieved the WHO recommended validity criteria that protective effect ≥50% and lower limit of 95% CI ≥30%. The results of the efficacy against COVID-19 cases of different severity showed that, the vaccine efficacy against moderate and severe cases was higher than that against mild cases, the efficacy was 100% (95%CI 50.15-100.00) against cases scored 3 and above.

In another ongoing study in Indonesia, the efficacy evaluation of 2 doses of SARS-CoV-2 vaccine in preventing COVID-19 was conducted (up to 6 months after the second dose of injection) in 1620 healthy subjects. The efficacy in preventing symptomatic confirmed cases of COVID-19 occurring at least 14 days after the second dose of vaccine was 51.98% with 17 COVID-19 cases occurred in the vaccine group and 35 COVID-19 cases in the placebo group.

PHARMACOKINETICS
Not applicable.

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

Genotoxicity/Carcinogenicity
Neither genotoxicity nor carcinogenicity studies were performed. The components of the vaccine are not expected to have genotoxic potential.

Reproductive Toxicity
Reproductive and developmental toxicity were investigated in male and female rats in a fertility and developmental toxicity study. Both male and female rats were intramuscularly administered with CoronaVac prior to mating. No significant adverse reaction was observed on the fertility of parental female and male rates, and gestation/lactation female rats. No embryo-foetal developmental toxicity and teratogenicity or effect on the growth and development of F1 pups was observed.

STORAGE CONDITIONS
Unopened vial (single-dose and multi-dose)
Store between +2ºC to +8ºC and protect from light. Do not freeze.

Multi-dose vial
After first puncture the vaccine (vial) can be stored at 2°C to 8°C for up to 6 hours or at room temperature (maximum 37°C) for a single period of up to 1 hour. Discard any unused vaccine if is not kept within the recommended conditions.

Keep medicine out of reach of children.

SHELF LIFE
Unopened vial (single-dose and multi-dose)
36 months.

Multi-dose vial
For shelf-life after first puncture, refer section **Storage Conditions**.

DOSAGE FORMS AND PACKAGING AVAILABLE
This product is packaged into vial, 40 vials per box.

PRODUCT REGISTRATION HOLDER
Pharmaniaga LifeScience Sdn Bhd
(198201002939)
Lot 7, Jalan PPU 3,
Taman Perindustrian Puchong Utama,
47100 Puchong,
Selangor, Malaysia

MANUFACTURER
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REGISTRATION NUMBER
MAL21036010ARZ

DATE OF REVISION
14th Dec 2023