FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF CORONAVAC

Badan POM, the Indonesia Food and Drug Administration, has issued **an Emergency Use Authorization (EUA)** to permit the emergency use of CoronaVac. CoronaVac is a vaccine which may prevent from getting COVID-19. Read this Fact Sheet for information about CoronVac prior to provide vaccination

The Emergency Use Authorization of the CoronaVac is to induce immunity against SARS-CoV-2 for the prevention of COVID-19. This product is suitable for people aged 18 – 59 years old**.**

CoronaVac is contraindicated in person who is:

1. hypersensitive to any component of this vaccine, or
2. Primary Immunodeficiency.

ADMINISTRATION:

The recommended route of administration is intramuscular injection at deltoid muscle. Shake well before use.

For emergency situation, the immunization schedule is 2 doses at 2-week interval (0 and 14 days), each dose is 0,5 mL.

Booster dose has not yet been determined.

CoronaVac is available as a suspension for injection packed in a 0,5 mL vial.

This product contains no preservative.

See the Full EUA Prescribing Information for complete dosage, administration, and preparation instructions.

Health care providers must submit a report on all medication errors and **ALL SERIOUS ADVERSE EVENTS** related to CoronaVac.

This Fact Sheet may have been updated. For more recent Fact Sheet see www.pom.go.id

For information on clinical trials that are testing the use of CoronaVac in COVID-19, please see www.clinicaltrials.gov

INSTRUCTIONS FOR ADMINISTRATION

This section provides essential information on the use of of CoronaVac which is to induce immunity against SARS-CoV-2 for the prevention of COVID-19. This product is suitable for people aged 18 – 59 years old.

Please refer to this fact sheet for information on use of CoronaVac under the EUA.

Composition

Each dose (0.5 mL) contains Inactivated SARS-COV-2 virus 3 mcg/dose.

The vaccine is an opalescent suspension, stratified precipitate may form which can be dispersed by shaking.

Excipients : Aluminium hydroxide, disodium hydrogen phosphate, sodium dihydrogen phosphate, sodium chloride, sodium hydroxide and HCl as pH adjuster.
This product contains no preservative.

Indication

This Vaccine stimulates body to induce immunity against SARS-CoV-2 for the prevention of COVID-19. This product is suitable for people aged 18 – 59 years old.

Contraindications

This product is contraindicated in person who:

- hypersensitive to any component of this vaccine
- Primary Immunodeficiency.

Dosage and Administration

The recommended route of administration is intramuscular injection at deltoid muscle. Shake well before use.
For emergency situation, the immunization schedule is 2 doses at 2-week interval (0 and 14 days), each dose is 0,5 mL.
Booster dose has not yet been determined.

<u>Special populations</u>

Elderly

No adequate safety and efficacy data available for the use of vaccine in elderly (60 years and above).

Paediatric population

The safety and efficacy of CoronaVac in children under the age of 18 years have not yet been established. No data are available.

IMPORTANT:

This product contains no preservative. Any unused portion of a single-dose CoronaVac vial should be discarded after a diluted solution is prepared.

WARNINGS

1. For patients in the acute illness period and/or in the acute attack of chronic disease, the vaccination should be postponed.
2. Under the following circumstances, the use of this vaccine should be carefully used :
   a. In patients with thrombocytopenia or bleeding/coagulation disorders, intramuscular injection of this vaccine may cause bleeding.
   b. Patients who have any history of confirmed or suspected immunosuppressive or immunodeficient state. Patients who are receiving immunosuppressive therapy or with immunodeficiency (intravenous immunoglobulins, blood-derived products or long-term corticosteroid therapy (> 2 weeks), the immune response to the vaccine may be weakened (see Drug Interactions). Vaccination should be deffered until the end of treatment on ensured patients to be well protected.
   c. Patients with uncontrolled epilepsy and other progressive neurological disorders such as Guillain-Barre Syndrome.
   d. Autoimmune disease
   e. History of asthma and severe adverse reactions to vaccines, such as urticaria, dyspnea, and angioneurotic edema
   f. Patients with serious chronic diseases (serious cardiovascular diseases, uncontrolled hypertension, uncontrolled diabetes, liver and kidney diseases, malignant tumors, etc).
3. The vaccine should not be administered concomitantly with other vaccines (see drug interactions).
4. Intravascular injection of this vaccine is strictly prohibited
5. Epinephrine injection and other appropriate agents and devices should be available to control immediate serious allergic reactions. Recipients should be observed on site for at least 30 minutes after vaccination.
6. As with any vaccine, vaccination with this product may not protect 100% of individuals
7. The vaccine must be kept out of reach of children
8. Do not expose the disinfectant to the vaccine when opening the vaccine vial and injection
9. Do not use if the vaccine bottle is cracked, poorly marked or ineffective, or if there is a foreign matter in the vaccine bottle.
10. Do not combine this product with other vaccines in the same syringe. Do not freeze this product. The vaccine should be used immediately after it is open.

DRUG INTERACTIONS

Concomitant administration of other vaccines: there has been no clinical studies on the effect of concomitant (pre, post or simultaneous) administration of other vaccines on the immunogenicity of this vaccine. There is no data available to assess the effect of simultaneopus administration of this product with other vaccines.

Immunosuppressive drugs : immunity inhibitor, chemotherapy drugs, antimetabolites. Alkylating agents, cittoxic crugs, corticosteorids etc, may reduce the body's immune response to this vaccine.

Patients who are receiving treatment : for those who are using the drug, it is recommended to consult a professional physician before receiving the vaccine to avoid possible drug interaction.

FERTILITY, PREGNANCY AND LACTATION

There is no safety and efficacy data available for the use of CoronaVac in the pregnancies and in the breastfeeding women.

ADVERSE REACTIONS

The Frequencies of adverse events are defined as follows: Very common (≥1/10 or ≥10%); common (≥1/100 to <1/10 or ≥1% to <10%); uncommon (≥1/1,000 to <1/100 or ≥0.1% to <1%); rare (≥1/10,000 to <1/1,000 or ≥0.01% to <0.1%).

According to the clinical trial conducted in China, Indonesia and Turkey, overall adverse event of CoronaVac reported in these studies were mild and moderate.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of CoronaVac Vaccine was evaluated in participants between 18 to 59 years of age in one phase 1/2 clinical studies conducted in China and 3 clinical studies conducted in Indonesia, Turkey and Brazil.

Phase 1 Clinical Study in China

Phase 1 clinical trial of CoronaVac in China involved 143 participants which included in the safety analysis that consists of 72 in vaccine group received 0-14 day regimen and 71 participants in vaccine group received 0-28 regimen. Total adverse events observed up to 28 days after two injections from all groups were 25.00%, which consists of 29.17% from medium dose group (600 SU), 37.50% from high dose group (1200 SU) and 8.33% from placebo group. The most common adverse events were pain in the site of injection and fatigue. Adverse events appeared more in the high dose group than in the medium dose group. Most of the adverse events reported as mild (grade 1), only 1 case (hypersensitive) was grade 3. No serious adverse event reported in the phase 1 clinical trial.

Phase 2 Clinical Study in China

Phase 2 clinical trial of CoronaVac in China involved 350 participants. In overall, total subjects reported adverse events in the 0-14 day regimen were 37%. 31.6% of them were related to the intervention (33.33% in the medium-dose group, 35.00% in the high-dose group and 21.67% the placebo group). In the 0-28 day regimen, the overall subjects reported adverse events were 27.67% and 19% of them were related to the intervention (19.00% in the medium-dose group, 19.17% in the high-dose group and 18.33% the placebo group).

Table 1. Incidence of AE after vaccination for emergency schedule (0-14 day) in phae II

Adverse events	Medium(N=120)		High(N=120)		Placebo(N=60)		Total(N=300)		P Value*
	No. of events	No. (%)	No. of events	No. (%)		No. of events	No. (%)	No. of events	
Overall adverse events	74	47(39.17)	88	50(41.67)	25	14(23.33)	187	111(37.00)	0.0447
Adverse events non-related to vaccination	15	11(9.17)	19	15(12.50)	5	4(6.67)	39	30(10.00)	0.4738
Adverse events related to vaccination	59	40(33.33)	69	42(35.00)	20	13(21.67)	148	95(31.67)	0.1626
Local	34	28(23.33)	43	33(27.50)	8	6(10.00)	85	67(22.33)	0.0218
Systemic	25	19(15.83)	26	16(13.33)	12	9(15.00)	63	44(14.67)	0.8695
Solicited	56	39(32.50)	64	40(33.33)	20	13(21.67)	140	92(30.67)	0.2455
Unsolicited	3	3(2.50)	5	3(2.50)	0	0(0.00)	8	6(2.00)	0.6564
Within 30 mins	11	11(9.17)	7	7(5.83)	4	3(5.00)	22	21(7.00)	0.5863
0~7days	59	40(33.33)	69	42(35.00)	20	13(21.67)	148	95(31.67)	0.1626
First dose	33	24(20.00)	39	29(24.17)	13	10(16.67)	85	63(21.00)	0.5182
Second dose	26	20(16.67)	30	20(16.81)	7	6(10.00)	63	46(15.38)	0.4429

*P value is calculated using Fisher exact probability method.

Phase 3 Clinical Study in Indonesia

Phase 3 clinical study in Indonesia involved 1620 participants in total. Overall 71.5 participants reported adverse events in all group in this study and appeared similar in the vaccine group and in the placebo group (71,6% vs 71,1%).

Table 2. Incidence of AE After First and Second Vaccination

Adverse Events	Vaccine (N=405)		Placebo (N=135)		Total (N=540)		p-value*
	No. of events	No. of subjects (%)	No. of events	No. of subjects (%)	No. of events	No. of subjects (%)	
Overall adverse events	1099	290 (71.6)	263	96(71.1)	1362	386 (71.5)	0.912
Local	402	208 (51.3)	96	60 (44.4)	498	268 (49.6)	0.164
Systemic	697	237 (58.5)	167	74 (54.8)	864	311 (57.6)	0.450
Solicited	741	255 (63.0)	151	73 (54.0)	892	328 (60.7)	0.067
Local	391	206 (50.9)	95	59 (43.7)	486	265 (49.1)	0.149
Systemic	350	170 (41.9)	56	34 (25.2)	406	204 (37.7)	**<0.001**
Unsolicited	358	182 (45.0)	112	59 (43.7)	470	241 (44.6)	0.803
Local	11	10 (2.4)	1	1 (0.7)	12	11 (2.0)	0.218
Systemic	347	177 (43.7)	111	59 (43.7)	458	236 (43.7)	1.000
Within 30 mins	280	145 (35.8)	111	64 (47.4)	391	209 (38.7)	**0.016**
0-7 days	632	225 (55.6)	84	45 (33.3)	716	270 (50.0)	**<0.001**
>7 days	187	111 (27.4)	68	38 (28.1)	255	149 (27.6)	0.867
After first dose	600	245 (60.5)	134	68 (50.4)	734	313 (57.9)	**0.039**
After second dose	499	206 (51.9)	129	72 (54.1)	628	278 (52.4)	0.619

*p-value is calculated using chi-square test.

Local reactions reported after first and second vaccination in both vaccine and placebo groups were local pain, redness, induration and swelling. Systemic events reported after first and second vaccination in both vaccine and placebo groups were myalgia, fatigue and fever.

Table 3. Comparison of Adverse Events between Vaccine and Placebo Group

Adverse events	After First Vaccination			After Second Vaccination		
	Vaccine (n =405)	Placebo (n= 135)	p-value*	Vaccine (n=397)	Placebo (n=133)	p-value*
Local reactions:						
Local pain	131 (32.3)	29 (21.5)	0.017	121 (30.5)	40 (30.1)	0.930
Redness	25 (6.2)	5 (3.7)	0.278	17(4.3)	3 (2.3)	0.288
Induration	34 (8.4)	6 (4.4)	0.129	29 (7.3)	6 (4.5)	0.262
Swelling	9 (2.2)	1 (0.7)	0.269	14 (3.5)	1 (0.8)	0.095
Systemic events:						
Fever	10 (2.5)	-	0.130	7 (1.8)	2 (1.5)	0.841
Fatigue	69 (17.0)	12 (8.9)	0.022	53 (13.3)	9 (6.8)	0.041
Myalgia	101 (24.9)	17 (12.6)	0.003	75 (18.9)	12 (9.0)	0.008

*p-value is calculated using Chi-square test.

Most of all adverse events reported as mild to moderate (grade 1 and 2). Adverse events grade 3 was reported less in vaccine group than in placebo group (7.4% vs 13.3%). Local reactions grade 3 reported in the vaccine group after first and second injections were local pain (1.0%) and swelling (0.3%). Systemic adverse events grade 3 reported in the vaccine group after first and second injections were fever (1.5%), myalgia (1.0%) and fatigue (0.7%). Adverse events un-solicited grade 3 were un-common reported in the vaccine group. AE un-solicited grade 3 reported until 7 days after injections were rhinitis (0.3%), pharyngitis (0.2%), abdominal pain (0.3%), dyspepsia (0.3%), nausea (0.5%), vomiting (0.3%), urticaria (0.3%), dizziness (0.5%), headache (1.0%), increasing appetite (0.3%), malaise (0.3%) and pyrexia (0.3%). No serious adverse events related to the vaccination reported in this study.

Clinical Phase 3 Study in Turkey

According to the data per 23 December 2020, safety analysis were conducted in 2964 subjects, where among them there were 593 subjects reported 1049 adverse events. Overall, CoronaVac showed good safety profile. Safety analysis for 7 days after first vaccination showed the local adverse events of CoronaVac were similar with placebo (9,45% vs 8,39%) and systemic adverse events less than in placebo (61.86% vs 75.16%). The most frequent systemic AE reported 7 days after first vaccination were fatigue (4.7%) and headache (3.9%). Local adverse events reported after second vaccination were also similar between vaccine group and placebo (0.98% vs 0.60%). The most frequent systemic adverse events after second vaccination were fatigue (2.5%) dan headache (2.3%). Adverse events reported for both local and systemic were mild and moderate (grade 1 and 2). Local AE grade 3 reported after first vaccination were local pain which was reported by 1 subject in vaccine and placebo group. No local AE reported after second vaccination. Systemic adverse events reported after first and second vaccination were headache (2 in vaccine group and 1 in placebo group), myalgia (1 in vaccine group), COVID symptoms (in placebo group), allergic reaction (1 in vaccine group) and hypertension (1 in placebo group). One case of serious adverse event is likely to be related to vaccination, which was allergy and the subject has recovered.

Table 4. Comparison of Adverse Events between Vaccine and Placebo Group after First and Second Dose

	First Dose		Second Dose	
	Vaccine	Placebo	Vaccine	Placebo
	N = 603	N= 310	N = 1221	N= 830
Local Adverse Events (AE)	**57**	**26**	**12**	**5**
Within 7 days				
grade 1	54	24	11	5
grade 2	2	1	0	0
grade 3	1	1	0	0
Systemic Adverse Events (AE)	**373**	**233**	**180**	**163**
Within 7 days				
grade 1	203	130	100	81
grade 2	36	20	24	17
grade 3	4	3	0	1
Systemic AE between 7 to 14 days after first dose / between 7 to 28 days after second dose				
grade 1	28	28	21	34
grade 2	10	8	5	6
grade 3	2	2	0	0

Phase 3 Clinical Study in Brazil

Safety report from phase 3 clinical study in Brazil received were from 7913 participants, nevertheless. Safety analysis conducted were overall and no comparison analysis between vaccine and placebo yet provided.

Total, there were 6803 (87.9%) participants reported adverse events 7 days after first vaccination, which consisted of 5,200 participants reported solicited local AE (1606; 20.29% participants), systemic AE (354; 4.47% participants), and un-solicited AE (1603; 20.7% participants). The most frequent solicited local AE reported after first injection was local pain and for solicited systemic AE were headache, fatigue, diarrhe and myalgia. Un-solicited local and systemic AE were sneezing (0.7%), nasal congestion (0.6%), oropharyngeal (1%), and Rhinorrhoea (2.4%). The adverse events reported 7 days after first dose mostly as mild to moderate (grade 1 and 2).

Totally. there were 2,722 (63.1%) participants who received 2 doses reported AEs after 7 days, in which consists of 2130 (27,25%) participants reported solicited local AE (871; 20.19% participants), systemic AE (1,213; 28.12% participants), and un-solicited AE (1603; 20.7% participants). The most frequent solicited local AE reported after second injection was local pain (18.6%) and for solicited

systemic AE were headache (11.4%), fatigue (3.8%), and myalgia (2.2%). Un-solicited systemic AE were Rhinorrhoea (1.3%) and oropharyngeal (0.6%). The adverse events reported 7 days after second dose mostly as mild to moderate (grade 1 and 2).

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Mechanism of action

SARS-CoV-2 Vaccine (Vero Cell), Inactivated developed by Sinovac Life Sciences Co. Ltd., can induce active immunity and prevent diseases caused by the disease by producing neutralizing antibody.

Preclinical Studies

Acute toxicity studies conducted on mice and rats showed no toxicity reaction was observed at dose of 1200 SU. The maximum tolerable dose is 1200 SU/animal. Sub-acute toxicity studies in cynomolgus monkeys showed that administration of the vaccine doses at 300 SU/injection and 1200 SU/injection did not cause toxicity. Muscle irritation test studies in rabbits showed that administration of the vaccine doses at 1200 SU/injection did not cause irritation reactions and significant pathophysiological changes at the injection site. Systemic anaphylaxis studies showed that vaccine doses at 120 SU, 240 SU, 1200 SU and 2400 SU did not cause anaphylaxis reactions in guinea pigs.

CLINICAL STUDIES

Immunogenicity

Phase 1 study of adult subjects in China

Immunogenicity analysis in Phase 1 clinical studies was carried out for 2 types of regimens, emergency regimen (0-14 days) and the routine regimen (0-28 days), as well as 2 different doses, the medium dose (600 SU-proposed dose) and the High-dose (1200 SU). The results of IgG immunogenicity observations 6 months after administration of the second dose of the emergency regimen (0-14 days) showed a decrease in the percentage of seropositive rate in both the group receiving the medium dose (from 87.50% to 33.33%) and the group receiving the high dose. (from 100% to 70.83%). The results of IgG immunogenicity observations 6 months after administration of the second dose of routine regimen (0-28 days) showed a decrease in the percentage of seropositive rate in both the group receiving the medium dose (from 100% to 62.50%) and the group receiving the high dose (from 100% to 79.17%).

The results of IgM immunogenicity observations 6 months after administration of the second dose of the emergency regimen (0-14 days) showed a decrease in the percentage of seropositive rate in both the group receiving the medium dose (from 12.5% to 0%) and the group receiving the high dose (from 20.83% to 8.33%). IgM data on routine regimens (0-28 days) also showed a reduction profile as in the emergency regimen both at medium dose and high dose, where the seropositive rate fell from 20.83% to 4.17 at 6 months after the second dose.

Phase 2 study of adult subjects in China

In the emergency regimen (0-14 days), the NAb value after 28 days of both medium dose and high dose were 94.07% and 99.15%, respectively. The seropositive rate for the IgG test after 6 months of the second dose of medium dose was 77.97% and for IgM was 1.69%.

Phase 3 study of adult subjects in Indonesia

The study aimed to assess the efficacy, immunogenicity, and safety of SARS-COV2 vaccine compared to placebo. The study design was a phase 3 clinical, RCT, observer blind, placebo-controlled study. A total of 1620 subjects participated in the study with inclusion criteria of healthy subjects aged 18-59 years.

The results of the IgG antibody test at 3 months after the second dose showed seropositive rate was 99.23%. The GMT value at 3 months after the second dose (1605.90), decrease 3.2 times compared to 14 days after the second dose (5181.19). The results of the antibody neutralization (NAb) test at 3 months after the second dose showed the percentage of the seropositive rate from 95.72% to 83.85%. The GMT value at 3 months after the second dose fell 2.2x (from 15.76 to 7.12) compared to 14 days after the second dose.

Efficacy

Efficacy of CoronaVac was evaluated according to the interim analysis of 3 phase 3 clinical studies conducted in Indonesia, Turkey and Brazil. The 3 clinical studies are continuing for follow-up.

According to interim analysis of the phase 3 clinical study in Indonesia (cut-off date 8 January 2021) which involved 1,620 adult participants with age between 18 -59 years, the assessment of the efficacy of 2 doses of SARS-CoV-2 vaccine in preventing COVID-19 infection compared to placebo, measured based on symptomatic cases confirmed by RT-PCR testing ranging from 14 days to 6 months after the second dose. The interim analysis of efficacy conducted based on the cut-off date of 8 January 2021 with a total of 25 cases of COVID--19 (as specified in the protocol for the minimum cases target to show VE 60% up to 90 days after the second injection) is 65.3%. The 25 cases consist of 7 cases in the vaccine group and 18 cases in the placebo group. The duration of observation for the calculation of this efficacy analysis is based on observations of up to 90 days (3 months), where in line with the efficacy observation criteria outlined by WHO for COVID-19 vaccines. From the 25 cases occurred, no severe, critical or death cases due to COVID-19 reported.

According to the interim analysis of the phase 3 clinical trial in Turkey (cut-off date 23 December 2020) which involved 13,000 adult participants with age between 18 and 59 years, the efficacy of CoronaVac vaccine was evaluated from 29 cases of COVID-19. The phase 3 clinical study in Turkey showed the vaccine efficacy was 91.25% (29 cases: 3 cases from vaccine group and 26 cases from placebo group) in the population aged 18-59 years, calculated based on the cut-off date of December 25, 2020 with a total of 29 cases of COVID19 (out of a target of 40 cases) from 1,322 participants.

A phase 3 clinical study conducted in Brazil which involved total approximately 13,060 participants (cut-off 9 January 2021). According to the information received, the vaccine efficacy of 78% (218 cases, 58 cases from vaccine group and 160 cases from placebo group) in a population ≥ 18 years. The COVID-19 cases occurred were all reported as mild cases.

STORAGE CONDITIONS

Do not re-use or save un-used of CoronaVac vaccine. This product contains no preservative.
CoronaVac suspension for injection is intended for single use.
Store CoronaVac suspension for injection vials between 2 – 8 °C. Do not use after expiration date.

INSTRUCTIONS FOR HEALTH CARE PROVIDERS

As the health care provider, you must communicate to your patient or parent/caregiver information consistent with the "**Informasi Produk untuk Pasien** (Fact Sheet for Patients and Parents/Caregivers)" (and provide a copy of the Fact Sheet) prior to the patient receiving CoronaVac, including:

1. That the Badan POM has authorized emergency use of CoronaVac
2. The potential consequences of refusing CoronaVac
3. The significant known and potential risks and benefits of CoronaVac, as supplied under this EUA.
4. The alternative products that are available and their benefits and risks, including clinical trials.

MANDATORY REQUIREMENTS FOR CORONAVAC ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION:

A. In order to mitigate the risks of using this product under EUA and to optimize the potential benefit of CoronaVac, the following items are required. Use of CoronaVac under this EUA is limited to the following (all requirements **must** be met):

1. CoronaVac is used to induce immunity against SARS-CoV-2 for the prevention of COVID-19. This product is suitable for people aged 18 – 59 years old.
2. As the health care provider, communicate to your patient or parent/caregiver information consistent with the "**Informasi Produk untuk Pasien**" prior to the patient receiving CoronaVac. Health care providers (to the extent practicable given the circumstances of the emergency) must document in the patient's medical record that the patient/caregiver has been:
    a. Given the "**Informasi Produk untuk Pasien**",
    b. Informed of alternatives to receiving CoronaVac, and
    c. Informed that CoronaVac is an unapproved drug that is authorized for use under Emergency Use Authorization.
3. Subjects with known hypersensitivity to any ingredient of CoronaVac must not receive CoronaVac.
4. The prescribing health care provider and/or the provider's designee are/is responsible for mandatory responses to requests from Badan POM for information about adverse events and medication errors following receipt of CoronaVac.
5. The prescribing health care provider and/or the provider's designee are/is responsible for mandatory reporting of all medication errors and adverse events (death, serious adverse events*) considered to be potentially related to CoronaVac occurring after vaccination within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "**CoronaVac under Emergency Use Authorization (EUA)**" in the description section of the report.

    - Submit adverse event reports to:

      Pusat Farmakovigilans/MESO Nasional

      Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif

Badan Pengawas Obat dan Makanan https://e-meso.pom.go.id/ADR

- Submitted reports should include in the field name, "Describe Event, Problem, or Product Use/Medication Error" the statement **"CoronaVac vaccination under EUA"**

*Serious Adverse Events are defined as:

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

B. The on-going phase 3 trial in Indonesia and or other clinical trial in other countries must be completed as required by the approved clinical trial protocol and clinical trial result must be reported to Badan POM accordingly.

APPROVED AVAILABLE ALTERNATIVES

There are EUAs for other COVID-19 treatments. The health care provider should visit https://clinicaltrials.gov/ to determine whether the patient may be eligible for enrollment in a clinical trial.

AUTHORITY FOR ISSUANCE OF THE EUA

Indonesian Government has declared an emergency situation as a result of pandemic outbreak of COVID-19 that justifies the emergency need of using CoronaVac as an treatment option in this situation. In response to that situation, the Badan POM has issued an Emergency Use Authorization (EUA) for the use of the Badan POM-approved product CoronaVac is to induce immunity against SARS-CoV-2 for the prevention of COVID-19. This product is suitable for people aged 18 – 59 years old.

As a health care provider, you must comply with the mandatory requirements of the EUA listed above.

Although the phase 3 clinical data is still on going, it is reasonable to believe that CoronaVac is effective to induce immunity against SARS-CoV-2 for the prevention of COVID-19. This product is suitable for people aged 18 – 59 years old, as specified in this Fact Sheet. You may be contacted and asked to provide information to help with the assessment of the use of the product during this emergency. Serious adverse events related to the use of CoronaVac must be reported to Badan POM through Pusat Farmakovigilans/MESO Nasional, Badan Pengawas Obat dan Makanan online http://e-meso.pom.go.id/ADR. Please include in the field name, "Describe Event, Problem, or Product Use/Medication Error" the following statement: **CoronaVac Vaccination under Emergency Use Authorization (EUA).**

This EUA for CoronaVac will end when the Badan POM determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

HARUS DENGAN RESEP DOKTER
ON MEDICAL PRESCRIPTION ONLY

Packaging: Box, 40 vial @ 0,5 ml (1 dose)

Manufactured by:
Sinovac Life Sciences, China

Imported and marketed by:
PT. Bio Farma
Bandung - Indonesia