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

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

The Emergency Use Authorization of the KconecaVac is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older. The use of this vaccine should be in accordance with official recommendations.

KconecaVac is contraindicated in person who is Hypersensitivity to the active substance or to any of the excipients listed in section **Composition**.

ADMINISTRATION:
Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection to be administered intramuscularly. Do not shake the vial.

The KconecaVac vaccination course consists of two separate doses of 0.5ml each. The second dose should be administered between 4 and 12 weeks, preferably between 8 and 12 weeks, after the first dose. (see section Pharmacodynamic Properties)

It is recommended that individuals who receive a first dose of KconecaVac complete the vaccination course with KconecaVac. (see section Special warnings and precautions for use).
Efficacy and safety data are currently limited in individuals ≥65 years of age (see sections Undesirable Effects and Pharmacodynamic Properties). No dosage adjustment is required.

The safety and efficacy of KconecaVac in children and adolescents (aged <18 years old) have not yet been established. No data are available.

KconecaVac is available as a solution for injection packed in a 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 KconecaVac.

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 KconecaVac, please see www.clinicaltrials.gov

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INSTRUCTIONS FOR ADMINISTRATION

This section provides essential information on the use of KconecaVac is for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

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

Composition

Each dose (0.5 mL) contains COVID-19 Vaccine (ChAdOx1-S* recombinant) 5×10^{10} viral particles (vp).

**Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.*

This product contains genetically modified organisms (GMOs).

The vaccine is a solution for injection. The solution is colourless to slightly brown, clear to slightly opaque and particle free with a pH of 6.6.

Excipients: L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dihydrate, and Water for injections.

Indication

KconecaVac is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

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

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section **Composition**.

Dosage and Administration

The KconecaVac vaccination course consists of two separate doses of 0.5ml each. The second dose should be administered between 4 and 12 weeks, preferably between 8 and 12 weeks, after the first dose. (see section Pharmacodynamic Properties)

It is recommended that individuals who receive a first dose of KconecaVac complete the vaccination course with KconecaVac. (see section Special warnings and precautions for use).

Special populations

Elderly population

Efficacy and safety data are currently limited in individuals ≥65 years of age (see sections Undesirable Effects and Pharmacodynamic Properties). No dosage adjustment is required.

Paediatric population

The safety and efficacy of KconecaVac in children and adolescents (aged <18 years old) have not yet been established. No data are available.

Method of administration

KconecaVac is for intramuscular (IM) injection only, preferably in the deltoid muscle.

IMPORTANT for Administration

The vaccine should be inspected visually prior to administration and discarded if particulate matter or differences in the described appearance are observed. Do not shake the vial.

Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual. Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5 ml dose is administered.

Where a full 0.5 ml dose cannot be extracted, the remaining volume should be discarded.

The vaccine does not contain any preservative. Aseptic technique should be used for withdrawing the dose for administration.

After first dose withdrawal, use the vial as soon as practically possible and within 6 hours (stored at 2°C to 25°C). Discard any unused vaccine.

To facilitate the traceability of the vaccine, the name and the batch number of the administered product should be clearly recorded for each recipient.

Disposal

KconecaVac contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in accordance with local requirements. Spills should be disinfected with an appropriate antiviral disinfectant.

SPECIAL WARNINGS AND PRECAUTIONS TO USE

Traceability

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

Hypersensitivity

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Concurrent illness

As with other vaccines, administration of KconecaVac should be postponed in individuals suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders

A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with KconecaVac. The percentage of incidence of this combine disease in United Kingdom and several European countries are presented under the **Adverse Reaction Section.** This combined disease includes severe cases presenting as venous thrombosis which usually found as venous, lung and artery thrombosis. Nevertheless, rare cases, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. Some cases had a fatal outcome. The majority of these cases occurred within the first fourteen days following vaccination and occurred mostly in women under 50 years of age. Some cases have increased D-dimer levels >4000ng/mL, positive platelet factor 4 antibodies and/or laboratory evidence of platelet activation.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain following vaccination.

Additionally, anyone with neurological symptoms including severe or persistent headaches or blurred

vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

According to the safety data of the use of KconecaVac in The United Kingdom and several European countries, the incidence of thrombocytopenia accompanied with blood clotting, either thrombosis occurred in the common sites or in the rare sites.

Meanwhile the Adverse Event Following Immunization (AEFI) report of the KconecaVac in Indonesia up to the issuance of this factsheet shows no case related to the thrombocytopenia along with thrombosis.

Nevertheless, the adverse events occurred in the United Kingdom and several European countries should be cautioned in the vaccination use the KconecaVac, where the incidence of thrombocytopenia with thrombosis is more common in the age of 50 years and below compared to the age of above 50 years and in women found more frequent than in men.

Risk of bleeding with intramuscular administration

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), because bleeding or bruising may occur at injection site n in these individuals.

Immunocompromised individuals

It is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressant therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen.

Duration and level of protection

The duration of protection has not yet been established.
As with any vaccine, vaccination with KconecaVac may not protect all vaccine recipients.

Interchangeability

No data are available on the use of KconecaVac in persons that have previously received a full or partial vaccine series with another COVID-19 vaccine.

Sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, and is considered to be essentially sodium-free.

Effects on ability to drive and use machines

KconecaVac has no or negligible influence on the ability to drive and use machines. However, some of the adverse reactions mentioned under **section Adverse Reactions** may temporarily affect the ability to drive or use machines.

Elderly

Efficacy and safety data are currently limited in individuals ≥65 years of age, the vaccine should be carefully used in Elderly. The vaccine should not be administered in frail elderly.

DRUG INTERACTIONS

No interaction studies have been performed.

Concomitant administration of KconecaVac with other vaccines has not been studied (see section Pharmacodynamics Properties).

Immunosuppressive drugs, such as: immunity inhibitor, chemotherapy drugs, antimetabolites, alkylating agents, citotoxic drugs, and corticosteroids, may reduce the body's immune response to this vaccine.

For patients who are receiving drug treatment, it is recommended to consult a professional physician before receiving the vaccine to avoid possible drug interaction.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy

There is a limited experience with the use of KconecaVac in pregnant women. Preliminary animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryofetal development, parturition or post-natal development; definitive animal studies have not been completed yet. The full relevance of animal studies to human risk with vaccines for COVID-19 remains to be established.

Administration of KconecaVac in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

Breastfeeding

It is unknown whether KconecaVac is excreted in human milk.

Fertility

Preliminary animal studies do not indicate direct or indirect harmful effects with respect to fertility.

ADVERSE REACTIONS

Summary of the safety profile

The overall safety of KconecaVac is based on an interim analysis of pooled data from four clinical trials conducted in the United Kingdom, Brazil, and South Africa. At the time of analysis, 23,745 participants ≥18 years old had been randomised and received either KconecaVac or control. Out of these, 12,021 received at least one dose of KconecaVac and 8,266 received two doses. The median duration of follow-up in the KconecaVac group was 105 days post-dose 1, and 62 days post-dose 2.

Demographic characteristics were generally similar among participants who received KconecaVac and those who received control. Overall, among the participants who received KconecaVac, 90.3% were aged 18 to 64 years and 9.7% were 65 years of age or older. The majority of recipients were White (75.5%), 10.1% were Black and 3.5% were Asian; 55.8% were female and 44.2% male.

The most frequently reported adverse reactions were injection site tenderness (63.7%); injection site pain (54.2%), headache (52.6%), fatigue (53.1%); myalgia (44.0%), malaise (44.2%); pyrexia (includes feverishness (33.6%) and fever >38°C (7.9%), chills (31.9%); and arthralgia (26.4%), nausea (21.9%).

The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. By day 7 the incidence of subjects with at least one local or systemic reaction was 4% and 13% respectively.

When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently. Reactogenicity was generally milder and reported less frequently in older adults (≥65 years old). The safety profile was consistent across participants with or without prior evidence of SARS-CoV-2 infection at baseline; the number of seropositive participants at baseline was 718 (3.0%).

Adverse reactions were generally milder and reported less frequently in older adults (≥65 years old). If required, analgesic and/or anti-pyretic medicinal products (e.g. paracetamol-containing products) may be used to provide symptomatic relief from post-vaccination adverse reactions.

There were two serious adverse events reported by two subjects in the clinical study considered as related to the KconecaVac, which are pyrexia and myelitis transverse.
Adverse Events Special Interest (AESI) reported in the clinical studies were paraesthesia (0.3% in KconecaVac group vs 0.4% in the control group), hypoaesthesia (0.1% in KconecaVacgroup vs 0.2% in control group), and muscular weakness (0.1% in KconecaVac group vs 0.1% in control group).

Tabulated list of adverse reactions

Adverse drug reactions (ADRs) are organised by MedDRA System Organ Class (SOC). Within each SOC, preferred terms are arranged by decreasing frequency and then by decreasing seriousness.
Frequencies of occurrence of adverse reactions are defined as: very common (≥1/10); common (≥ 1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (<1/10,000) and not known (cannot be estimated from available data).

Table 1 Adverse drug reactions

MedDRA SOC	Frequency	Adverse Reactions
Blood and lymphatic system disorders	Uncommon	Lymphadenopathy[a]
Metabolism and nutrition disorders	Uncommon	Decreased appetite[a]
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness[a]
Gastrointestinal disorders	Very common	Nausea
	Common	Vomiting
	Uncommon	Abdominal pain[a]
Skin and subcutaneous tissue disorders	Uncommon	Hyperhidrosis[a], pruritus[a], rash[a]
Musculoskeletal and connective tissue disorders	Very common	Myalgia, arthralgia
General disorders and administration site conditions	Very common	Injection site tenderness, injection site pain, injection site warmth, injection site erythema, injection site pruritus, injection site swelling, injection site bruising[b], fatigue, malaise, pyrexia[c], chills
	Common	Injection site induration, influenza-like illness[a]

a Unsolicited adverse reaction
b Injection site bruising includes injection site haematoma (uncommon, unsolicited adverse reaction)
c Pyrexia includes feverishness (very common) and fever ≥38°C (common)

Very rare events of neuroinflammatory disorders have been reported following vaccination with KconecaVac. A causal relationship has not been established.

Post Marketing Experience

The following adverse reactions were not observed during clinical trials and have been spontaneously reported during worldwide post-authorization use of KconecaVac.

The frequency of these adverse reactions is “not known” (cannot be estimated from available data as the reports come from a population of unknown size).
Immune system disorder: Anaphylactic reaction

Skin and subcutaneous tissue disorders: Angioedema

A very rare case of Thrombosis with thrombocytopaenia has been reported in UK and EU. As of 4 April 2021, a total of 169 cases of CVST and 53 cases of splanchnic vein thrombosis were reported to EudraVigilance. Around 34 million people had been vaccinated in the EEA and UK by 7 April 2021.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties Mechanism of action

KconecaVac is a monovalent vaccine composed of a single recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector encoding the S glycoprotein of SARS-CoV-2. Following administration, the S glycoprotein of SARS-CoV-2 is expressed locally stimulating neutralising antibody and cellular immune responses.

Preclinical Studies

Non-clinical data reveal no special hazard for humans based on a conventional study of repeat dose toxicity. Animal studies into potential toxicity to reproduction and development have not yet been completed.

CLINICAL STUDIES

Immunogenicity

Following vaccination with KconecaVac, in participants who were seronegative at baseline, seroconversion (as measured by a ≥4 fold increase from baseline in S-binding antibodies) was demonstrated in ≥98% of participants at 28 days after the first dose and >99% at 28 days after the second. Higher S-binding antibodies were observed with increasing dose interval (Table 3). Generally similar trends were observed between analyses of neutralising antibodies and S-binding antibodies. An immunological correlate of protection has not been established; therefore the level of immune response that provides protection against COVID-19 is unknown.

Table 3 SARS CoV-2 S-binding antibody response to KconecaVaca, b

N = Number of subjects included in each group; GMT = Geometric mean titre; CI = Confidence interval;
S = Spike
a Immune response evaluated using a multiplex immunoassay; b in individuals who received two recommended doses of vaccine.

The immune response observed in participants with one or more comorbidities was consistent with the overall population.

High seroconversion rates were observed in older adults (≥65 years) after the first (97.8%; N=136) and

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the second recommended dose (100.0%; N=111). The increase in S-binding antibodies was lower for participants ≥65 years old (28 days after second dose: GMT=20,727.02 [N=116, 95% CI: 17,646.6; 24,345.2]) when compared to participants aged 18-64 years (28 days after second dose: GMT=30,695.30 [N=703, 95% CI: 28,496.2; 33,064.1]). The majority of participants ≥65 years old had a dose interval of <6 weeks, which may have contributed to the lower titres observed.

In participants with serological evidence of prior SARS-CoV-2 infection at baseline (GMT=13,137.97 [N=29; 95% CI: 7,441.8; 23,194.1]), S-antibody titres peaked 28 days after dose 1 (GMT=175,120.84 [N=28; 95% CI: 120,096.9; 255,354.8]).
Spike-specific T cell responses as measured by IFN-ɣ enzyme-linked immunospot (ELISpot) assay were induced after a first dose of KconecaVac. These did not rise further after a second dose.

Efficacy
KconecaVac has been evaluated based on an interim analysis of pooled data from four on-going randomised, blinded, controlled trials: a Phase I/II Study, COV001, in healthy adults 18 to 55 years of age in the UK; a Phase II/III Study, COV002, in adults ≥18 years of age (including the elderly) in the UK; a Phase III Study, COV003, in adults ≥18 years of age (including the elderly) in Brazil; and a Phase I/II study, COV005, in adults aged 18 to 65 years of age in South Africa. The studies excluded participants with history of anaphylaxis or angioedema; participants with severe and/or uncontrolled cardiovascular, gastrointestinal, liver, renal, endocrine/metabolic disease, and neurological illnesses; as well as those with immunosuppression. In studies COV001 and COV002, licensed seasonal influenza and pneumococcal vaccinations were permitted (at least 7 days before or after their study vaccine).

All participants are planned to be followed for up to 12 months, for assessments of safety and efficacy against COVID-19 disease.

Based on the pre-defined criteria for interim efficacy analysis, COV002 and COV003 exceeded the threshold of ≥5 virologically confirmed COVID-19 cases per study and therefore contributed to the efficacy analysis; COV001 and COV005 were excluded.

In the pooled analysis for efficacy (COV002 and COV003), participants ≥18 years of age received two doses of KconecaVac (N=5,807) or control (meningococcal vaccine or saline) (N=5,829). Because of logistical constraints, the interval between dose 1 and dose 2 ranged from 4 to
26 weeks.

Baseline demographics were well balanced across KconecaVac and control treatment groups. Overall, among the participants who received KconecaVac,
94.1% of participants were 18 to 64 years old (with 5.9% aged 65 or older); 60.7% of subjects were female; 82.8% were White, 4.6% were Asian, and 4.4% were Black. A total of 2,070 (35.6%) participants had at least one pre-existing comorbidity (defined as a BMI ≥30 kg/m2, cardiovascular disorder, respiratory disease or diabetes). The median follow-up time post-dose 1 and post-dose 2 was 132 days and 63 days, respectively.

Final determination of COVID-19 cases were made by an adjudication committee, who also assigned disease severity according to the WHO clinical progression scale. A total of 131 participants had SARS-CoV-2 virologically confirmed (by nucleic acid amplification tests) COVID-19 occurring ≥15 days post-dose 2 with at least one COVID-19 symptom (objective fever (defined as ≥37.8oC), cough, shortness of breath, anosmia, or ageusia) and were without evidence of previous SARS-CoV-2 infection. KconecaVac significantly decreased the incidence of COVID-19 compared to control (see
Table 2).

Table 2 KconecaVac efficacy against COVID-19

Population	COVID-19 Vaccine AstraZeneca		Control		Vaccine efficacy % (CI)
	N	Number of COVID-19 cases, n (%)	N	Number of COVID-19 cases, n (%)	
Primary (see above)	**5,807**		**5,829**		
COVID-19 cases		30 (0.52)		101 (1.73)	70.42 (54.84, 80.63)[a]
Hospitalisations[b]		0		5 (0.09)	-
Severe disease[c]		0		1 (0.02)	-
Any dose	**10,014**		**10,000**		
COVID-19 cases after dose 1		108 (1.08)		227 (2.27)	52.69 (40.52, 62.37)[d]
Hospitalisations after dose 1[b]		2 (0.02)[e]		16 (0.16)	-
Severe disease after dose 1[c]		0		2 (0.02)	

N = Number of subjects included in each group; n = Number of subjects having a confirmed event;
CI = Confidence Interval; a 95.84% CI; b WHO severity grading ≥4; c WHO severity grading ≥6; d 95% CI; e Two cases of hospitalisation occurred on Days 1 and 10 post vaccination.

The level of protection gained from a single dose of KconecaVac was assessed in an exploratory analysis that included participants who had received one dose. Participants were censored from the analysis at the earliest time point of when they received a second dose or at 12 weeks post-dose 1. In this population, vaccine efficacy from 22 days post-dose 1 was 73.00% (95% CI: 48.79; 85.76 [KconecaVac 12/7,998 vs control 44/7,982]).

Exploratory analyses showed that increased immunogenicity was associated with a longer dose interval (see Immunogenicity Table 3). Efficacy is currently demonstrated with more certainty for dose intervals from 8 to 12 weeks. Data for intervals longer than 12 weeks are limited.

Participants who had one or more comorbidities had a vaccine efficacy of 73.43% [95% CI: 48.49; 86.29]; 11 (0.53%) vs 43 (2.02%) for KconecaVac (N=2,070) and control (N=2,113), respectively; which was similar to the vaccine efficacy observed in the overall population.

The number of COVID-19 cases (2) in 660 participants ≥65 years old were too few to draw conclusions on efficacy. However, in this subpopulation, immunogenicity data are available, see **immunogenicity**.

STORAGE
CONDITIONS
This product contains no preservative.

Unopened multidose vial
Store in a refrigerator (2 to 8°C). Do not freeze. Keep vials in outer carton to protect from light.
The approved shelf life is 6 months.

After first use
Use as soon as practically possible and within 6 hours.
The vaccine may be stored between 2°C and 25°C during the in-use period.

INSTRUCTIONS FOR HEALTH CARE PROVIDERS
As the health care provider, you must communicate to your patient or parent/caregiver information consistent with the "**Informasi untuk Peserta Vaksinasi** (Fact Sheet for Vaccinees and Parents/Caregivers)" (and provide a copy of the Fact Sheet) prior to the patient receiving KconecaVac, including:

1. That the Badan POM has authorized emergency use of KconecaVac
2. The potential consequences of refusing KconecaVac
3. The significant known and potential risks and benefits of KconecaVac, as supplied under

this EUA.

4. The alternative products that are available and their benefits and risks, including clinical trials.

MANDATORY REQUIREMENTS FOR KCONECAVAC 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 KconecaVac, the following items are required. Use of KconecaVac under this EUA is limited to the following (all requirements must be met):

1. KconecaVac is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older

2. As the health care provider, communicate to your vaccinees or parent/caregiver information consistent with the "**Informasi untuk Peserta Vaksinasi**" prior to the patient receiving KconecaVac. 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 untuk Peserta Vaksinasi**",
   b) Informed of alternatives to receiving KconecaVac, and
   c) Informed that KconecaVac is an unapproved drug that is authorized for use under Emergency Use Authorization.

3. Subjects with known hypersensitivity to any ingredient of KconecaVac must not receive KconecaVac.

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 KconecaVac.

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 KconecaVac occurring after vaccination within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "**KconecaVac di bawah Persetujuan Penggunaan Darurat (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 **"KconecaVac di bawah Persetujuan Penggunaan Darurat (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 KconecaVac as a treatment option in this situation. In response to that situation, the Badan POM has issued an Emergency Use Authorization (EUA) for the use of KconecaVac is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.
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 KconecaVac is effective for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older, 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 KconecaVac 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: **KconecaVac di bawah Persetujuan Penggunaan Darurat (EUA).**

This EUA for KconecaVac 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:
Multidose vial: 5 ml of solution in a 10-dose vial (clear type I glass) with a halobutyl rubber stopper and an aluminium overseal with a plastic flip-off cap. Packs of 10 vials.

Manufactured and released by:

Shenzhen Kangtai Biological Products Co., Ltd., China

Imported by:

PT. Bio Farma, Indonesia

EUA Number:

EUAXXXXXXXXXX