Version 1.0

Convidecia™

First Approval Date: MM DD YYYY

FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF CONVIDECIA VACCINE FOR INHALATION

Badan POM, the Indonesia Food and Drug Administration, has issued **an Emergency Use Authorization (EUA)** to permit the emergency use of Convidecia™ Vaccine for Inhalation. Convidecia Vaccine for Inhalation is a vaccine which is intended to prevent from getting COVID-19 disease in adults ages 18 years and older. The Convidecia™ Vaccine for Inhalation (short name Ad5-nCoV-IH) is administrated using a nebulized inhalation device. Read this Fact Sheet for information about Convidecia™ Vaccine for Inhalation prior tovaccination

The Emergency Use Authorization of the Convidecia™ Vaccine for Inhalation is intended to prevent the COVID-19 disease caused by the SARS-CoV-2 virus in adults 18 years and older. The use of this vaccine should be in accordance with official recommendations.

Convidecia™ Vaccine for Inhalation is contraindicated in person who is Hypersensitive to the active substance or to any of the excipients listed in the **Composition** section.

ADMINISTRATION:

A single dose (0.1ml) for nebulized inhalation by oral through using a nebulized inhalation device described in the **Dosage and Administration** section.

Convidecia™ Vaccine for Inhalation is available as a solution for nebulized inhalation packed in a 2 mL vials. 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 Convidecia™ Vaccine for Inhalation.

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 Convidecia™ Vaccine for Inhalation, please see www.clinicaltrials.gov

INSTRUCTIONS FOR ADMINISTRATION

This section provides essential information on the use of Convidecia™ Vaccine for Inhalation is intended to use to prevent theCOVID-19 disease caused by the SARS-CoV-2 virus in adults 18 years and older.

Please refer to this fact sheet for information on use of the Convidecia™ Vaccine for Inhalation under the EUA.

Composition

Each glass vial of Convidecia™ Vaccine for Inhalation contains 0.5ml or 1.5 mL liquid injection, containing 10.0 $\times 10^{10}$ VP/ml of recombinant replication-defective human type 5 adenovirus expressing the S protein of SARS-CoV-2.

The excipients include Mannitol, sucrose, sodium chloride, magnesium chloride, polysorbate 80, glycerin, and N-(2-Hydroxyethyl) piperazine-N'-(2-ethanesulfonic acid) (HEPES) and Water-For-Injection as solvent.

Indication

Convidecia™ Vaccine for Inhalation is indicated for booster immunization of individuals ages 18 years and older for the prevention of the coronavirus disease, COVID-19, caused by the SARS-CoV-2, with an interval of 3 months and longer after completing the primary immunization with Sinovac COVID-19 inactivated vaccines.

Contraindications

(1) Allergic reaction to any component of this vaccine (included excipients).

(2) People who have experienced severe allergic reactions to vaccines in the past (such as acute allergic reactions, angioedema, dyspnea, etc.).

(3) People with uncontrolled epilepsy and other progressive neurological diseases, and the history of Guillain-Barré syndrome.

Dosage and Administration

The Convidecia™ Vaccine for Inhalation can be administered (0.1ml/dose) by inhalation at least 3 months after completing the primary immunization with Sinovac COVID-19 inactivated vaccines in individuals 18 years of age and older.

Special populations

Elderly population

No dosage adjustment is required in elderly individuals $\geqslant$ 60 years of age.

Paediatric population

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

Method of administration

The vaccine is delivered by inhalation using a nebulized inhalation device. Please refer to the "Guideline for Installation and Use of Nebulized Inhalation Device" for the detailed device information and direction for use.

Nebulized Inhalation Device and Operation Steps

Nebulized inhalation device is the vaccine delivery system. The main component is the nebulizer which is used to nebulize the liquid vaccine to aerosol. With regard to how to use the Nebulized Inhalation Device is briefly described as follows:

1) Setting up of the Nebulized Inhalation Device (Figure 1) according to the installation steps

of Guideline for Installation and Use of Nebulized Inhalation Device.

2) Get the Disposable Aerosol Container (DAC) ready.

3) Inject 0.1ml liquid vaccine into the nebulizer, set a timer for 25 seconds and start the nebulization.

4) After starting nebulization for 25 seconds, press the On/Off power button to close nebulization.

5) Deliver the DAC to the vaccine recipient immediately (Figure 2A).

6) Vaccine recipient should exhale deeply from lungs before receiving the vaccine (Figure 2B). Do not exhale directly onto the DAC.

7) The vaccine recipient puts his/her mouth over the DAC Inhalation Port and inhales the nebulized vaccine slowly and deeply through the Inhalation Port of DAC. Stop inhalation until the aerosol is invisible (Figure 2C). Complete the inhalation within 15 seconds after finishing the nebulization process.

8) The vaccine recipient should hold the breath for at least 5 seconds (Figure 2D) and then the vaccination is complete.

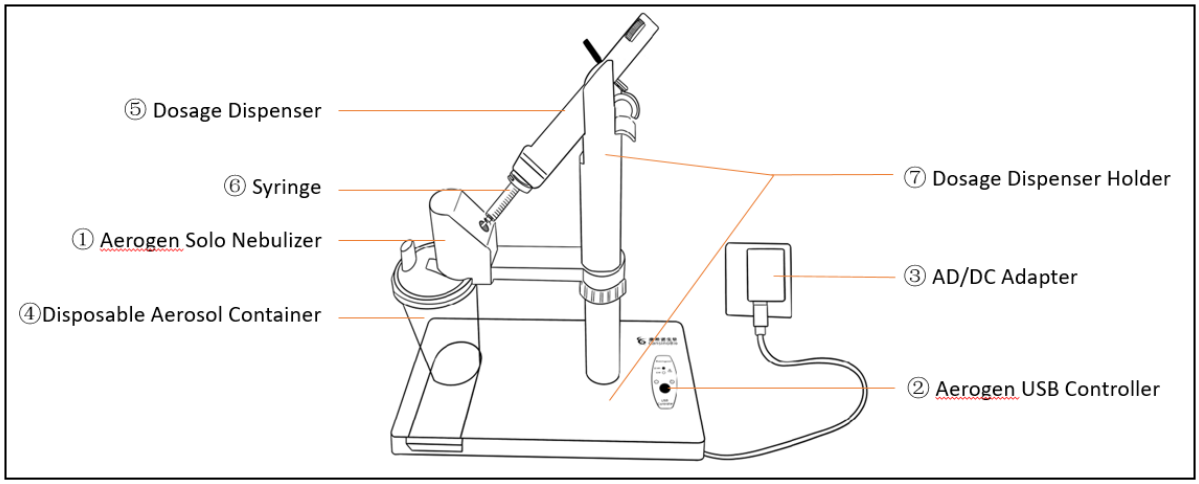

Figure 1 Nebulized Inhalation Device

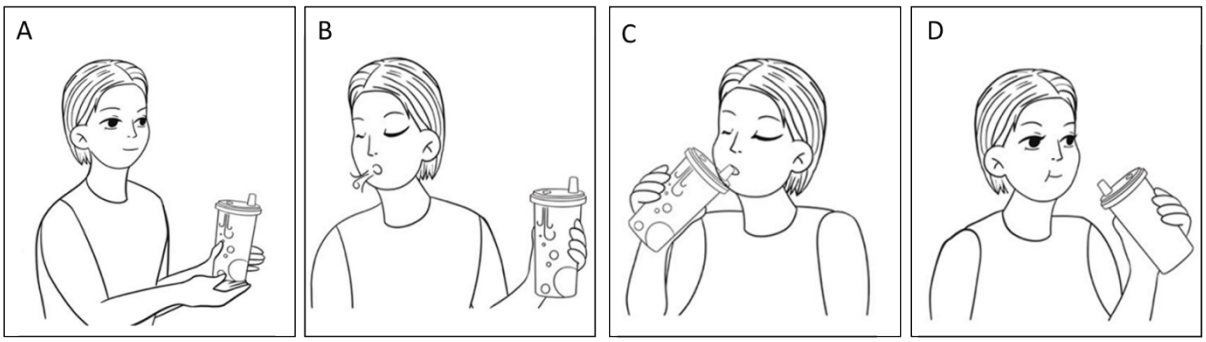

Figure 2 Inhalation of Nebulized Vaccine

IMPORTANT for Administration

The vaccine should be inspected visually prior to administration and discarded if particulate matter ordifferences in the described appearance are observed.
The vaccine is prohibited to mix with other vaccine(s) in the same inhalation device at the same time.
The vaccine does not contain any preservative. Aseptic technique should be used for withdrawing thedose for administration.
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
Any unused vaccine or waste material should be disposed of in compliance with the local guidance forgenetically modified organisms or biohazardous waste. Spills should be disinfected using agents with activity against adenovirus.

SPECIAL WARNINGS AND PRECAUTIONS TO USE

(1) 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.

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

(3) Concurrent illness. As with other vaccines, administration of Convidecia™ Vaccine for Inhalation should be postponed inindividuals suffering from an acute severe febrile illness. As well as, the presence of a minor infection, such as cold, and/or low-grade fever should also delay vaccination.

(4) 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.

(5) Duration and level of protection. The duration of protection has not yet been established.

(6) As with any vaccine, vaccination with Convidecia™ Vaccine for Inhalation may not protect all vaccine recipients

(7) Interchangeability. No data are available on the use of Convidecia™ Vaccine for Inhalation in persons that have previouslyreceived a full or partial vaccine series with another COVID-19 vaccine.

(8) Effects on ability to drive and use machines. Convidecia™ Vaccine for Inhalation 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.

(9) People suffering from acute diseases, acute-outbreak period of chronic diseases, severe chronic diseases, allergies and fever should be used with caution. If necessary, the vaccination shall be delayed after the doctor's evaluation.

(10) Cautionary use for those with history of convulsions, epilepsy, encephalopathy or mental illness or family history.

(11) Cautionary use for those with a history of asthma, chronic obstructive pulmonary disease, pulmonary fibrosis and other underlying diseases or abnormal pulmonary function.

(12) People who have any neurological adverse reactions after vaccination of Convidecia™ Vaccine for Inhalation are prohibited from re-vaccination.

(13) There is no evidence of the efficacy of Convidecia™ Vaccine for Inhalation for people with SARS-CoV-2 infection history at this point.

(14) People with positive HIV infection. There is very limited data available for this vaccine in HIV positive population. It is recommended that the use of this vaccine in people with positive HIV infection should be strictly under physicians' guidance.

(15) It is prohibited to mix Convidecia™ Vaccine for Inhalation with other vaccine(s) in the same inhalation device.

(16) Convidecia™ Vaccine for Inhalation should be used as soon as possible after opening. It should not be used for more than 6 hours after opening. It should be discarded if less than 0.1 ml is left.

(17) Avoid vaccine exposure to disinfectant when opening the vaccine vial.

(18) People who are vaccinated should be observed on site according to the local general vaccination practice (at least 30 minutes). The vaccination clinic should be equipped with first-aid drugs and equipment such as epinephrine to deal with the emergency such as severe acute allergic reaction.

(19) Those who have been injected with immune globulin should vaccinate Convidecia™ Vaccine for Inhalation at an interval of more than 1 month to avoid decreasing the immune effect.

(20) During the inhalation process (including the 5-second breath holding period), if the inhalation fails due to coughing or exhalation in advance, it is necessary to re-inhale one dose of vaccine. Only one repeated inhalation is allowed.

DRUG INTERACTIONS

(1) Simultaneous vaccination with other vaccines: No undergone clinical trial for simultaneous vaccination with other vaccines.

(2) Concomitant use with other drugs: no relevant data is available for immunosuppressants, chemotherapeutics, antimetabolites, alkylating agents, cytotoxic drugs, corticosteroids, etc., which may reduce the immune response of Convidecia™ Vaccine for Inhalation.

For people received or is receiving drug therapy, the consultancy of professional physician is required to avoid possible drug interactions.

FERTILITY, PREGNANCY AND LACTATION

(1) Women of childbearing age: The data collected in clinical trials for women who have unintended pregnancy after Convidecia™ Vaccine for Inhalation vaccination is very limited. It is not enough to assess the risk of adverse pregnancy outcomes (including spontaneous abortion) after vaccination with Convidecia™ Vaccine for Inhalation.

(2) Pregnant or lactating women: The clinical trial data of Convidecia™ Vaccine for Inhalation for pregnant and lactating women are limited.

(3) Fertility: No direct or indirect harmful effects have been found based on the reproductive toxicity study.

ADVERSE REACTIONS

Summary of the safety profile

The safety of Convidecia™ vaccine for Inhalation was evaluated in the two booster clinical trials conducted in China: one is a single-center, randomized, open-label, parallel-controlled heterologous booster immunization clinical trial (NCT05043259); one is a multi-center, open-label, partially randomized controlled heterologous booster immunization clinical trial (NCT05204589).

A total of 423 subjects aged 18 and older who have received two-dose of inactivated COVID-19 vaccine, were enrolled in the single center booster study clinical trial, of which 140 subjects were vaccinated with Ad5-nCoV-IH vaccine with 0.1ml (NCT05043259). A total of 10,219 subjects aged 18 and older were enrolled in the multi-center booster clinical trial, of which 10,011 subjects (3,482 subjects (34.78%) aged 60 years and older) were vaccinated with Ad5-nCoV-IH vaccine with 0.1ml (NCT05204589).

According to the classification of the incidence of adverse reactions recommended by the Council for International Organizations of Medical Sciences (CIOMS): very common (≥10%), common (1%~10%, including 1%), uncommon (0.1%~1%, including 0.1%), rare (0.01%~0.1%, including 0.01%), very rare (<0.01%), the safety data are summarized as follow:

Solicited adverse reactions

(1) Local adverse reaction

Common: dry mouth, oropharyngeal pain

Uncommon: dysphonia, pharyngeal swelling, oral mucositis;

Rare: oropharyngeal discomfort

(2) Systemic adverse reactions

Common: headache, fatigue, fever, cough, rhinorrhea, sneezing, arthralgia;

Uncommon: nausea, myalgia, diarrhea, decreased appetite, chest pain, itching, vomiting, mucocutaneous diseases.

Unsolicited adverse reactions*

Uncommon: dizziness, chest discomfort, abdominal discomfort, expectoration

Rare: non-infectious gingivitis, constipation, toothache, lip swelling, nasal obstruction, nasal dryness, chill, hidrosis, tinnitus, insomnia, dysphoria, pneumonia, upper respiratory tract infection, tonsillitis, otitis media, palpitation, increased heart rate, frequency of urination, dysuria, hypesthesia, eye discomfort, ulcer, dyspnea.

*Unsolicited adverse reactions reported following the booster dose, through 28 days after the booster dose, in participants over 18 years of age (N = 10,151), were assessed as adverse reactions not already captured by solicited local and systemic reactions.

Severity of adverse reactions

The severity of adverse reactions observed in clinical trials of the vaccine is mainly grade 1 (mild), the incidence of grade 3 and above adverse reactions is 0.36%, mainly fever symptoms, and no adverse reactions of grade 4 are reported.

Serious adverse event

No serious adverse events (SAEs) has been observed in the clinical trials.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Mechanism of action

Convidecia™ Vaccine for Inhalation is nebulized into mist with an average particle size < 5.5 micrometer through the nebulizer, which allows vaccinee to inhale the vaccine down to the lower respiratory tract. This procedure is similar to the natural infection of SARS-CoV-2. Once the vaccine reaches the respiratory tract and lungs, it will trigger the system to generate the S protein specific antibodies (e.g. IgG and secretory IgA), neutralizing antibodies as well as cellular immunity which are able to protect people from COVID-19.

Preclinical Studies

No special hazard for humans based on the single dose and repeated dose toxicity studies.
Genotoxicity/Carcinogenicity

Neither genotoxicity nor carcinogenicity studies were performed. The components of Convidecia™ Vaccine for Inhalation are not expected to have genotoxic potential.

Reproductive toxicity

The reproductive toxicity study in rats show no toxicity in dams or foetuses.

CLNICAL STUDIES

The immunogenicity of Convidecia™ vaccine for Inhalation was evaluated in a randomized, open-label, and parallel-controlled (inactivated COVID-19 vaccine and Ad5-nCoV vaccine) clinical trial (Phase II, NCT05043259) in healthy adults of 18 years. Participants received one dose of Convidecia™ Vaccine for Inhalation or inactivated vaccine at months 3-9 after completing the prime immunization with 2-dose inactivated COVID-19 vaccines. Compared with homologous prime immunization and booster immunization with inactivated vaccine, heterologous immunization with inactivated vaccine + Covidecia Vaccine for Inhalation could induce a higher antibody level.

The immunogenicity of Convidecia™ vaccine for Inhalation was further evaluated in the Phase III clinical (NCT05204589). This is a multicenter, open-label, parallel-randomized controlled clinical study in healthy adults of 18 years. Participants received one dose of Convidecia™ vaccine for Inhalation or inactivated vaccine after completing the prime immunization with 2-dose inactivated COVID-19 vaccines with the interval of at least 6 months.

The immunogenicity endpoint of this Convidecia™ Vaccine for Inhalation mainly included the geometric mean titer (GMT) of S-RBD IgG antibody, GMT neutralizing of neutralizing antibody and the response level of cellular immune index (IFN-γ). Neutralizing antibody was determined by micro cytophysiologic method, IFN-γ was determined by ELISpot method. The detailed information of Phase II and Phase III is shown as Table 1 and Table 2.

Table 1 Analysis results of S-RBD IgG antibody, neutralizing antibody and IFN-γ response level in Phase II clinical trial (NCT05043259)

Time after immunization	Group A* (N=138)		Group A* (N=40)
	GMT of S-RBD IgG antibody（95%CI）	GMT of Neutralizing antibody against wild type virus（95%CI）	Response level of IFN-γ（95%CI）
Day 0 of primary immunization	30.53 (25.76,36.20)	3.69 (3.26,4.17)	1.7 (1.0,2.4)
Day 7 after booster immunization	40.99 (33.13,50.73)	/	40.4 (23.6,57.2)
Day 14 after booster immunization	4630.80 (3523.02,6086.89)	692.07 (533.87,897.16)	28.1 (17.1,39.1)
Day 28 after booster immunization	6216.98 (5106.51,7568.93)	1316.28 (1090.06,1589.44)	/

*: low-dose heterologous booster immunization group

Table 2 Analysis results of S-RBD IgG antibody and neutralizing antibody in the Phase III clinical trial (NCT05204589)

Time after immunization	Ad5-nCoV-IH Group	Ad5-nCoV-IH Group
	N=212 for day 0, N=211 for Day 14, N=210 for Day 28, N=60 for Month 3)	N=212 for day 0, N=211 for Day 14, N=210 for Day 28, N=207 for Month 3
	GMT of S-RBD IgG antibody (95%CI)	GMT of Neutralizing antibody against Omicron BA.4/5 Strain (95%CI)
Day 0 of primary immunization	15.45 (13.32,17.90)	15.29 (15.03,15.56)
Day 14 after booster immunization	2747.44 (2077.48,3633.47)	91.41 (74.28,112.49)
Day 28 after booster immunization	5771.99 (4662.37,7145.70)	107.70 (88.76,130.67)
Month 3 after booster immunization	5475.58 (3684.94,8136.35)	64.06 (53.72,76.39)

STORAGE CONDITIONS

Unopened multi-dose vial:

It should be stored and transported in refrigerated conditions under 2-8°C.

Opened multi-dose vial:

Use as soon as practically possible and within 6 hours. The vaccine should be stored under room temperature during the in-use period. Discard any unused vaccine if it is not used within the time frame.

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 Convidecia™ Vaccine for Inhalation, including:

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

MANDATORY REQUIREMENTS FOR CONVIDECIA VACCINE FOR INHALATION ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

A. In order to mitigate the risks of using this product under EUA and to optimize the potential benefitof Convidecia™ Vaccine for Inhalation, the following items are required. Use of Convidecia™ Vaccine for Inhalation under this EUA is limited to the following (all requirements must be met):

1. Convidecia™ Vaccine for Inhalation is indicated for active immunization 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 Convidecia™ Vaccine for Inhalation. 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 Convidecia™ Vaccine for Inhalation, and
    c) Informed that Convidecia™ Vaccine for Inhalation is an unapproved drug that is authorized for use under Emergency Use Authorization.
3. Subjects with known hypersensitivity to any ingredient of Convidecia™ Vaccine for Inhalation must not receive this vaccine.
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 andmedication errors following receipt of Convidecia™ Vaccine for Inhalation.
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 Convidecia Vaccine for Inhalation occurring after vaccination within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "**Convidecia ™ Vaccine for Inhalation di bawah Persetujuan Penggunaan Darurat (EUA)**" inthe 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 "Convidecia™ Vaccine for Inhalation 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 conductnormal 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 some 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 clinicaltrial.

AUTHORITY FOR ISSUANCE OF THE EUA

Indonesian Government has declared an emergency situation as a result of pandemic outbreak of COVID-19that justifies the emergency need of using Convidecia™ Vaccine for Inhalation as a treatment option in this situation. In response to that situation, the Badan POM has issued an Emergency Use Authorization (EUA) for the useof Convidecia™ Vaccine for Inhalation is indicated for active immunization 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 Convidecia™ Vaccine for Inhalation is effective for active immunization 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 Convidecia™ Vaccine for Inhalation 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: **Convidecia™ Vaccine for Inhalation di bawah Persetujuan Penggunaan Darurat (EUA).**

This EUA for Convidecia™ Vaccine for Inhalation 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, 1 VIAL @ 0.5 ML (3 DOSES)

Or

BOX, 1 VIAL @ 1.5 ML (14 DOSES)

Manufactured by:

CANSINO BIOLOGICS INC.

185 South Avenue, TEDA West District Tianjin, China 300462

Imported and distributed by

PT. Etana Biotechnologies Indonesia

Jakarta – Indonesia

Prepared by CanSino Biologics Inc.

Version 1.0

Convidecia™

First Approval Date: MM DD YYYY

FACT SHEET FOR HEALTH CARE PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF CONVIDECIA VACCINE FOR INHALATION

Badan POM, the Indonesia Food and Drug Administration, has issued **an Emergency Use Authorization (EUA)** to permit the emergency use of Convidecia™ Vaccine for Inhalation. Convidecia Vaccine for Inhalation is a vaccine which is intended to prevent from getting COVID-19 disease in adults ages 18 years and older. The Convidecia™ Vaccine for Inhalation (short name Ad5-nCoV-IH) is administrated using a nebulized inhalation device. Read this Fact Sheet for information about Convidecia™ Vaccine for Inhalation prior tovaccination

The Emergency Use Authorization of the Convidecia™ Vaccine for Inhalation is intended to prevent the COVID-19 disease caused by the SARS-CoV-2 virus in adults 18 years and older. The use of this vaccine should be in accordance with official recommendations.

Convidecia™ Vaccine for Inhalation is contraindicated in person who is Hypersensitive to the active substance or to any of the excipients listed in the **Composition** section.

ADMINISTRATION:

A single dose (0.1ml) for nebulized inhalation by oral through using a nebulized inhalation device described in the **Dosage and Administration** section.

Convidecia™ Vaccine for Inhalation is available as a solution for nebulized inhalation packed in a 2 mL vials. This product contains no preservative.

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Health care providers must submit a report on all medication errors and **ALL SERIOUS ADVERSE EVENTS** related to Convidecia™ Vaccine for Inhalation.

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 Convidecia™ Vaccine for Inhalation, please see www.clinicaltrials.gov

INSTRUCTIONS FOR ADMINISTRATION

This section provides essential information on the use of Convidecia™ Vaccine for Inhalation is intended to use to prevent theCOVID-19 disease caused by the SARS-CoV-2 virus in adults 18 years and older.

Please refer to this fact sheet for information on use of the Convidecia™ Vaccine for Inhalation under the EUA.

Composition

Each glass vial of Convidecia™ Vaccine for Inhalation contains 0.5ml or 1.5 mL liquid injection, containing 10.0 $\times 10^{10}$ VP/ml of recombinant replication-defective human type 5 adenovirus expressing the S protein of SARS-CoV-2.

The excipients include Mannitol, sucrose, sodium chloride, magnesium chloride, polysorbate 80, glycerin, and N-(2-Hydroxyethyl) piperazine-N'-(2-ethanesulfonic acid) (HEPES) and Water-For-Injection as solvent.

Indication

Convidecia™ Vaccine for Inhalation is indicated for booster immunization of individuals ages 18 years and older for the prevention of the coronavirus disease, COVID-19, caused by the SARS-CoV-2, with an interval of 3 months and longer after completing the primary immunization with Sinovac COVID-19 inactivated vaccines.

Contraindications

(1) Allergic reaction to any component of this vaccine (included excipients).

(2) People who have experienced severe allergic reactions to vaccines in the past (such as acute allergic reactions, angioedema, dyspnea, etc.).

(3) People with uncontrolled epilepsy and other progressive neurological diseases, and the history of Guillain-Barré syndrome.

Dosage and Administration

The Convidecia™ Vaccine for Inhalation can be administered (0.1ml/dose) by inhalation at least 3 months after completing the primary immunization with Sinovac COVID-19 inactivated vaccines in individuals 18 years of age and older.

Special populations

Elderly population

No dosage adjustment is required in elderly individuals $\geqslant$ 60 years of age.

Paediatric population

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

Method of administration

The vaccine is delivered by inhalation using a nebulized inhalation device. Please refer to the "Guideline for Installation and Use of Nebulized Inhalation Device" for the detailed device information and direction for use.

Nebulized Inhalation Device and Operation Steps

Nebulized inhalation device is the vaccine delivery system. The main component is the nebulizer which is used to nebulize the liquid vaccine to aerosol. With regard to how to use the Nebulized Inhalation Device is briefly described as follows:

1) Setting up of the Nebulized Inhalation Device (Figure 1) according to the installation steps

of Guideline for Installation and Use of Nebulized Inhalation Device.

2) Get the Disposable Aerosol Container (DAC) ready.

3) Inject 0.1ml liquid vaccine into the nebulizer, set a timer for 25 seconds and start the nebulization.

4) After starting nebulization for 25 seconds, press the On/Off power button to close nebulization.

5) Deliver the DAC to the vaccine recipient immediately (Figure 2A).

6) Vaccine recipient should exhale deeply from lungs before receiving the vaccine (Figure 2B). Do not exhale directly onto the DAC.

7) The vaccine recipient puts his/her mouth over the DAC Inhalation Port and inhales the nebulized vaccine slowly and deeply through the Inhalation Port of DAC. Stop inhalation until the aerosol is invisible (Figure 2C). Complete the inhalation within 15 seconds after finishing the nebulization process.

8) The vaccine recipient should hold the breath for at least 5 seconds (Figure 2D) and then the vaccination is complete.

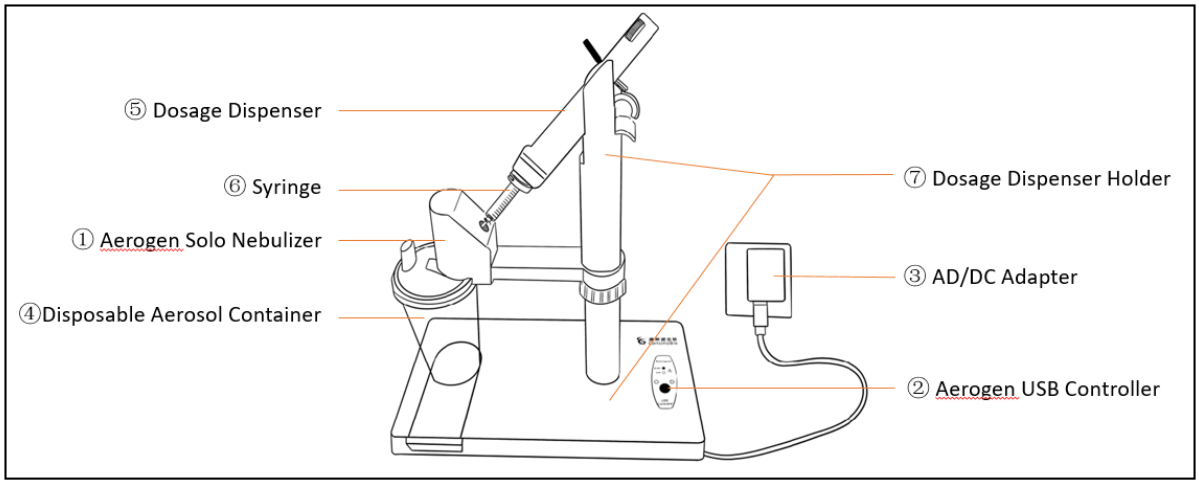

Figure 1 Nebulized Inhalation Device

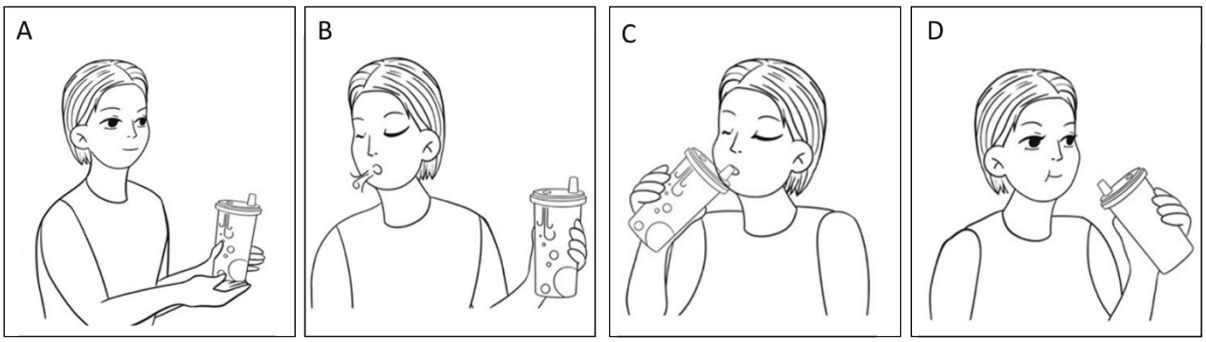

Figure 2 Inhalation of Nebulized Vaccine

IMPORTANT for Administration

The vaccine should be inspected visually prior to administration and discarded if particulate matter ordifferences in the described appearance are observed.
The vaccine is prohibited to mix with other vaccine(s) in the same inhalation device at the same time.
The vaccine does not contain any preservative. Aseptic technique should be used for withdrawing thedose for administration.
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
Any unused vaccine or waste material should be disposed of in compliance with the local guidance forgenetically modified organisms or biohazardous waste. Spills should be disinfected using agents with activity against adenovirus.

SPECIAL WARNINGS AND PRECAUTIONS TO USE

(1) 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.

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

(3) Concurrent illness. As with other vaccines, administration of Convidecia™ Vaccine for Inhalation should be postponed inindividuals suffering from an acute severe febrile illness. As well as, the presence of a minor infection, such as cold, and/or low-grade fever should also delay vaccination.

(4) 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.

(5) Duration and level of protection. The duration of protection has not yet been established.

(6) As with any vaccine, vaccination with Convidecia™ Vaccine for Inhalation may not protect all vaccine recipients

(7) Interchangeability. No data are available on the use of Convidecia™ Vaccine for Inhalation in persons that have previouslyreceived a full or partial vaccine series with another COVID-19 vaccine.

(8) Effects on ability to drive and use machines. Convidecia™ Vaccine for Inhalation 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.

(9) People suffering from acute diseases, acute-outbreak period of chronic diseases, severe chronic diseases, allergies and fever should be used with caution. If necessary, the vaccination shall be delayed after the doctor's evaluation.

(10) Cautionary use for those with history of convulsions, epilepsy, encephalopathy or mental illness or family history.

(11) Cautionary use for those with a history of asthma, chronic obstructive pulmonary disease, pulmonary fibrosis and other underlying diseases or abnormal pulmonary function.

(12) People who have any neurological adverse reactions after vaccination of Convidecia™ Vaccine for Inhalation are prohibited from re-vaccination.

(13) There is no evidence of the efficacy of Convidecia™ Vaccine for Inhalation for people with SARS-CoV-2 infection history at this point.

(14) People with positive HIV infection. There is very limited data available for this vaccine in HIV positive population. It is recommended that the use of this vaccine in people with positive HIV infection should be strictly under physicians' guidance.

(15) It is prohibited to mix Convidecia™ Vaccine for Inhalation with other vaccine(s) in the same inhalation device.

(16) Convidecia™ Vaccine for Inhalation should be used as soon as possible after opening. It should not be used for more than 6 hours after opening. It should be discarded if less than 0.1 ml is left.

(17) Avoid vaccine exposure to disinfectant when opening the vaccine vial.

(18) People who are vaccinated should be observed on site according to the local general vaccination practice (at least 30 minutes). The vaccination clinic should be equipped with first-aid drugs and equipment such as epinephrine to deal with the emergency such as severe acute allergic reaction.

(19) Those who have been injected with immune globulin should vaccinate Convidecia™ Vaccine for Inhalation at an interval of more than 1 month to avoid decreasing the immune effect.

(20) During the inhalation process (including the 5-second breath holding period), if the inhalation fails due to coughing or exhalation in advance, it is necessary to re-inhale one dose of vaccine. Only one repeated inhalation is allowed.

DRUG INTERACTIONS

(1) Simultaneous vaccination with other vaccines: No undergone clinical trial for simultaneous vaccination with other vaccines.

(2) Concomitant use with other drugs: no relevant data is available for immunosuppressants, chemotherapeutics, antimetabolites, alkylating agents, cytotoxic drugs, corticosteroids, etc., which may reduce the immune response of Convidecia™ Vaccine for Inhalation.

For people received or is receiving drug therapy, the consultancy of professional physician is required to avoid possible drug interactions.

FERTILITY, PREGNANCY AND LACTATION

(1) Women of childbearing age: The data collected in clinical trials for women who have unintended pregnancy after Convidecia™ Vaccine for Inhalation vaccination is very limited. It is not enough to assess the risk of adverse pregnancy outcomes (including spontaneous abortion) after vaccination with Convidecia™ Vaccine for Inhalation.

(2) Pregnant or lactating women: The clinical trial data of Convidecia™ Vaccine for Inhalation for pregnant and lactating women are limited.

(3) Fertility: No direct or indirect harmful effects have been found based on the reproductive toxicity study.

ADVERSE REACTIONS

Summary of the safety profile

The safety of Convidecia™ vaccine for Inhalation was evaluated in the two booster clinical trials conducted in China: one is a single-center, randomized, open-label, parallel-controlled heterologous booster immunization clinical trial (NCT05043259); one is a multi-center, open-label, partially randomized controlled heterologous booster immunization clinical trial (NCT05204589).

A total of 423 subjects aged 18 and older who have received two-dose of inactivated COVID-19 vaccine, were enrolled in the single center booster study clinical trial, of which 140 subjects were vaccinated with Ad5-nCoV-IH vaccine with 0.1ml (NCT05043259). A total of 10,219 subjects aged 18 and older were enrolled in the multi-center booster clinical trial, of which 10,011 subjects (3,482 subjects (34.78%) aged 60 years and older) were vaccinated with Ad5-nCoV-IH vaccine with 0.1ml (NCT05204589).

According to the classification of the incidence of adverse reactions recommended by the Council for International Organizations of Medical Sciences (CIOMS): very common (≥10%), common (1%~10%, including 1%), uncommon (0.1%~1%, including 0.1%), rare (0.01%~0.1%, including 0.01%), very rare (<0.01%), the safety data are summarized as follow:

Solicited adverse reactions

(1) Local adverse reaction

Common: dry mouth, oropharyngeal pain

Uncommon: dysphonia, pharyngeal swelling, oral mucositis;

Rare: oropharyngeal discomfort

(2) Systemic adverse reactions

Common: headache, fatigue, fever, cough, rhinorrhea, sneezing, arthralgia;

Uncommon: nausea, myalgia, diarrhea, decreased appetite, chest pain, itching, vomiting, mucocutaneous diseases.

Unsolicited adverse reactions*

Uncommon: dizziness, chest discomfort, abdominal discomfort, expectoration

Rare: non-infectious gingivitis, constipation, toothache, lip swelling, nasal obstruction, nasal dryness, chill, hidrosis, tinnitus, insomnia, dysphoria, pneumonia, upper respiratory tract infection, tonsillitis, otitis media, palpitation, increased heart rate, frequency of urination, dysuria, hypesthesia, eye discomfort, ulcer, dyspnea.

*Unsolicited adverse reactions reported following the booster dose, through 28 days after the booster dose, in participants over 18 years of age (N = 10,151), were assessed as adverse reactions not already captured by solicited local and systemic reactions.

Severity of adverse reactions

The severity of adverse reactions observed in clinical trials of the vaccine is mainly grade 1 (mild), the incidence of grade 3 and above adverse reactions is 0.36%, mainly fever symptoms, and no adverse reactions of grade 4 are reported.

Serious adverse event

No serious adverse events (SAEs) has been observed in the clinical trials.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Mechanism of action

Convidecia™ Vaccine for Inhalation is nebulized into mist with an average particle size < 5.5 micrometer through the nebulizer, which allows vaccinee to inhale the vaccine down to the lower respiratory tract. This procedure is similar to the natural infection of SARS-CoV-2. Once the vaccine reaches the respiratory tract and lungs, it will trigger the system to generate the S protein specific antibodies (e.g. IgG and secretory IgA), neutralizing antibodies as well as cellular immunity which are able to protect people from COVID-19.

Preclinical Studies

No special hazard for humans based on the single dose and repeated dose toxicity studies.
Genotoxicity/Carcinogenicity

Neither genotoxicity nor carcinogenicity studies were performed. The components of Convidecia™ Vaccine for Inhalation are not expected to have genotoxic potential.

Reproductive toxicity

The reproductive toxicity study in rats show no toxicity in dams or foetuses.

CLNICAL STUDIES

The immunogenicity of Convidecia™ vaccine for Inhalation was evaluated in a randomized, open-label, and parallel-controlled (inactivated COVID-19 vaccine and Ad5-nCoV vaccine) clinical trial (Phase II, NCT05043259) in healthy adults of 18 years. Participants received one dose of Convidecia™ Vaccine for Inhalation or inactivated vaccine at months 3-9 after completing the prime immunization with 2-dose inactivated COVID-19 vaccines. Compared with homologous prime immunization and booster immunization with inactivated vaccine, heterologous immunization with inactivated vaccine + Covidecia Vaccine for Inhalation could induce a higher antibody level.

The immunogenicity of Convidecia™ vaccine for Inhalation was further evaluated in the Phase III clinical (NCT05204589). This is a multicenter, open-label, parallel-randomized controlled clinical study in healthy adults of 18 years. Participants received one dose of Convidecia™ vaccine for Inhalation or inactivated vaccine after completing the prime immunization with 2-dose inactivated COVID-19 vaccines with the interval of at least 6 months.

The immunogenicity endpoint of this Convidecia™ Vaccine for Inhalation mainly included the geometric mean titer (GMT) of S-RBD IgG antibody, GMT neutralizing of neutralizing antibody and the response level of cellular immune index (IFN-γ). Neutralizing antibody was determined by micro cytophysiologic method, IFN-γ was determined by ELISpot method. The detailed information of Phase II and Phase III is shown as Table 1 and Table 2.

Table 1 Analysis results of S-RBD IgG antibody, neutralizing antibody and IFN-γ response level in Phase II clinical trial (NCT05043259)

Time after immunization	Group A* (N=138)		Group A* (N=40)
	GMT of S-RBD IgG antibody（95%CI）	GMT of Neutralizing antibody against wild type virus（95%CI）	Response level of IFN-γ（95%CI）
Day 0 of primary immunization	30.53 (25.76,36.20)	3.69 (3.26,4.17)	1.7 (1.0,2.4)
Day 7 after booster immunization	40.99 (33.13,50.73)	/	40.4 (23.6,57.2)
Day 14 after booster immunization	4630.80 (3523.02,6086.89)	692.07 (533.87,897.16)	28.1 (17.1,39.1)
Day 28 after booster immunization	6216.98 (5106.51,7568.93)	1316.28 (1090.06,1589.44)	/

*: low-dose heterologous booster immunization group

Table 2 Analysis results of S-RBD IgG antibody and neutralizing antibody in the Phase III clinical trial (NCT05204589)

Time after immunization	Ad5-nCoV-IH Group	Ad5-nCoV-IH Group
	N=212 for day 0, N=211 for Day 14, N=210 for Day 28, N=60 for Month 3)	N=212 for day 0, N=211 for Day 14, N=210 for Day 28, N=207 for Month 3
	GMT of S-RBD IgG antibody (95%CI)	GMT of Neutralizing antibody against Omicron BA.4/5 Strain (95%CI)
Day 0 of primary immunization	15.45 (13.32,17.90)	15.29 (15.03,15.56)
Day 14 after booster immunization	2747.44 (2077.48,3633.47)	91.41 (74.28,112.49)
Day 28 after booster immunization	5771.99 (4662.37,7145.70)	107.70 (88.76,130.67)
Month 3 after booster immunization	5475.58 (3684.94,8136.35)	64.06 (53.72,76.39)

STORAGE CONDITIONS

Unopened multi-dose vial:

It should be stored and transported in refrigerated conditions under 2-8°C.

Opened multi-dose vial:

Use as soon as practically possible and within 6 hours. The vaccine should be stored under room temperature during the in-use period. Discard any unused vaccine if it is not used within the time frame.

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 Convidecia™ Vaccine for Inhalation, including:

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

MANDATORY REQUIREMENTS FOR CONVIDECIA VACCINE FOR INHALATION ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

A. In order to mitigate the risks of using this product under EUA and to optimize the potential benefitof Convidecia™ Vaccine for Inhalation, the following items are required. Use of Convidecia™ Vaccine for Inhalation under this EUA is limited to the following (all requirements must be met):

1. Convidecia™ Vaccine for Inhalation is indicated for active immunization 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 Convidecia™ Vaccine for Inhalation. 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 Convidecia™ Vaccine for Inhalation, and
    c) Informed that Convidecia™ Vaccine for Inhalation is an unapproved drug that is authorized for use under Emergency Use Authorization.
3. Subjects with known hypersensitivity to any ingredient of Convidecia™ Vaccine for Inhalation must not receive this vaccine.
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 andmedication errors following receipt of Convidecia™ Vaccine for Inhalation.
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 Convidecia Vaccine for Inhalation occurring after vaccination within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words "**Convidecia ™ Vaccine for Inhalation di bawah Persetujuan Penggunaan Darurat (EUA)**" inthe 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 "Convidecia™ Vaccine for Inhalation 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 conductnormal 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 some 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 clinicaltrial.

AUTHORITY FOR ISSUANCE OF THE EUA

Indonesian Government has declared an emergency situation as a result of pandemic outbreak of COVID-19that justifies the emergency need of using Convidecia™ Vaccine for Inhalation as a treatment option in this situation. In response to that situation, the Badan POM has issued an Emergency Use Authorization (EUA) for the useof Convidecia™ Vaccine for Inhalation is indicated for active immunization 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 Convidecia™ Vaccine for Inhalation is effective for active immunization 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 Convidecia™ Vaccine for Inhalation 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: **Convidecia™ Vaccine for Inhalation di bawah Persetujuan Penggunaan Darurat (EUA).**

This EUA for Convidecia™ Vaccine for Inhalation 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, 1 VIAL @ 0.5 ML (3 DOSES)

Or

BOX, 1 VIAL @ 1.5 ML (14 DOSES)

Manufactured by:

CANSINO BIOLOGICS INC.

185 South Avenue, TEDA West District Tianjin, China 300462

Imported and distributed by

PT. Etana Biotechnologies Indonesia

Jakarta – Indonesia

Prepared by CanSino Biologics Inc.

INFORMASI PRODUK UNTUK PESERTA VAKSINASI MENGGUNAKAN *CONVIDECIA* UNTUK PENCEGAHAN COVID-19 PADA DEWASA USIA 18 TAHUN KEATAS

Anda diberikan *CONVIDECIA* untuk pencegahan COVID-19. Informasi Produk (PIL) ini mengandung informasi yang dapat membantu untuk mengetahui manfaat dan risiko penggunaan *CONVIDECIA* yang sudah atau akan anda terima.

Baca Informasi Produk ini untuk mengetahui informasi mengenai *CONVIDECIA*, bicarakan kepada tenaga kesehatan yang merawat Anda apabila ada pertanyaan lebih lanjut. Hal ini merupakan pilihan Anda untuk menggunakan *CONVIDECIA* atau menghentikannya.

APAKAH COVID-19?

COVID-19 merupakan penyakit yang disebabkan oleh virus yang disebut coronavirus SARS CoV-2. Jenis corona virus ini belum diketahui sebelumnya. Virus baru ini pertama kali ditemukan di Wuhan, Provinsi Hubei, China pada Desember 2019. Penyebaran dari orang ke orang telah dilaporkan di luar Hubei dan di negara selain China, termasuk di Indonesia. Anda dapat menderita COVID-19 melalui kontak dengan orang yang memiliki virus tersebut.

APA GEJALA DARI COVID-19?

Bila seseorang terinfeksi virus, dia akan menunjukkan gejala dalam 1-14 hari sejak terpapar virus. Gejala umumnya adalah demam, rasa lelah batuk, kering. Sebagian besar orang hanya akan mengalami gejala ringan, namun di kasus-kasus yang tertentu, infeksi dapat menyebabkan pnemonia dan kesulitan bernapas. Pada sebagian kecil kasus, infeksi virus corona bisa berakibat fatal.

Penyakit COVID-19 memiliki rentang keparahan dari sangat ringan hingga parah (termasuk beberapa laporan kasus tanpa gejala hingga parah, termasuk penyakit yang mengakibatkan kematian). Informasi yang ada sejauh ini menunjukkan sebagian besar penyakit COVID-19 bersifat ringan, namun penyakit serius dapat terjadi dan dapat menyebabkan beberapa kondisi medis Anda lainnya menjadi lebih buruk. Orang yang lebih tua dan orang dari segala usia dengan kondisi medis kronis yang parah, seperti penyakit jantung, penyakit paru-paru dan diabetes, berisiko lebih tinggi dirawat di rumah sakit apabila terjangkit COVID-19.

APA ITU *CONVIDECIA*?

CONVIDECIA dengan nama pendek Ad5-nCoV, merupakan Adenovirus tipe 5 rekombinan manusia replication-defective (rAd) yang mengekspresikan protein S SARS-CoV-2. Vaksin ini dapat membentuk kekebalan tubuh terhadap virus SARS-CoV-2 sehingga dapat mencegah penyakit COVID-19.

Badan POM memberikan izin penggunaan emergensi (darurat) *CONVIDECIA* inhalasi untuk vaksin booster heterolog setelah penggunaan vaksin COVID-19 inaktif Sinovac sebagai pencegahan COVID-19 pada dewasa usia 18 tahun keatas dengan interval vaksinasi 3 bulan atau lebih.

CONVIDECIA ini tidak melindungi 100% orang.

BERITAHUKAN PETUGAS KESEHATAN JIKA ANDA :

- Memiki alergi, termasuk alergi terhadap *CONVIDECIA* atau bahan lainnya yang terkandung dalam vaksin ini.
- Pernah memiliki riwayat alergi berat (seperti anafilaksis) setelah pemberian vaksin apapun sebelumnya.
- Memiliki epilepsi yang tidak terkontrol dan penyakit neurologis progresif lainnya, dan

EUA-Convidecia, Factsheet for healthcare provider,
Approved version date 17/02/2023, BPOM ID EREG10000712200086-87

riwayat sindrom Guillain-Barré.

- Sedang mengalami demam tinggi (suhu 38^{o}C atau lebih).
- Memiliki penyakit akut dan/atau serangan akut penyakit kronik. Jika terdapat kondisi ini, vaksinasi ditunda.
- Diduga atau terkonfirmasi mengalami imunodefisiensi (gangguan sisitem imun) atau sedang menggunakan terapi imunosupresif (penekan sistem imun) seperti immunoglobulin IV, produk darah, kortikosteroid jangka panjang, karena dapat menurunkan efek khasiat dari vaksin.
- Memiliki penyakit autoimun.
- Memiliki riwayat asma berat atau reaksi berat lainnya karena vaksin seperti urtikaria (biduran), dypnoea (sesak nafas), dan edema angioneurotic (bengkak, umumnya pada wajah dan bibir).
- Sedang memiliki penyakit serius (gangguan jantung serius, hipertensi yang tidak terkontrol, diabetes yang tidak terkontrol, penyakit hati/liver, penyakit ginjal, tumor dan kanker).
- Obat-obatan atau vaksin yang digunakan sebelumnya (dalam waktu dekat) atau sedang digunakan atau yang mungkin akan digunakan.
- Sedang hamil atau merencanakan kehamilan.
- Sedang menyusui.
- Pernah/sedang menderita COVID-19.

SIAPA YANG TIDAK BOLEH MENGGUNAKAN *CONVIDECIA*?

Jangan menggunakan *CONVIDECIA* jika sebelumnya Anda memiliki riwayat reaksi alergi terhadap vaksin, hipersensitif terhadap kandungan dari vaksin, memiliki penyakit gangguan sistem imun sejak lahir, atau memiliki epilepsi yang tidak terkontrol dan penyakit neurologis progresif lainnya, serta riwayat sindrom Guillain-Barré. Beritahukan dokter Anda atau petugas kesehatan bila ini terjadi pada Anda.

BAGAIMANA SAYA MENDAPATKAN *CONVIDECIA* ?

CONVIDECIA tersedia dalam bentuk cairan inhalasi.

Vaksin ini akan dimasukkan ke dalam *nebulizer* sebanyak 0,1 mL dosis tunggal untuk heterologous booster, kemudian dengan menggunakan *nebulized inhalation device*, cairan inhalasi diubah menjadi aerosol ke dalam *Disposable Aerosol Container (DAC)* untuk siap dihirup.

Penerima vaksin harus menghembuskan napas dalam-dalam dari paru-paru sebelum menerima vaksin. Jangan menghembuskan napas langsung ke DAC. Kemudian vaksin dihirup dari DAC secara perlahan dan dalam. Hentikan inhalasi sampai aerosol tidak terlihat pada DAC. Penerima vaksin harus menahan nafas minimal 5 detik. Kemudian vaksinasi selesai.

Vaksin heterologous booster diberikan setelah melengkapi imunisasi primer dengan vaksin inaktif COVID-19 Sinovac, direkomendasikan dengan interval vaksinasi 3 bulan atau lebih melalui *nebulized inhalation*.

BAHAN APA SAJA YANG TERKANDUNG DALAM *CONVIDECIA*?

Bahan aktifnya adalah Vaksin Rekombinan Novel Coronavirus (Adenovirus tipe 5), masing-masing dosis sebanyak 0,1 mL dengan kandungan $10{,}0\times10^{10}$ VP/mL Adenovirus tipe 5 rekombinan manusia replication-defective (rAd) yang mengekspresikan protein S.

Bahan lainnya adalah Manitol, sukrosa, natrium klorida, magnesium klorida, polisorbat 80, gliserin, dan N-(2-Hidroksietil) piperazina-N'-(2-asam etanasulfonat) (HEPES) dan Air untuk Injeksi sebagai pelarut.

EUA-Convidecia, Factsheet for healthcare provider,
Approved version date 17/02/2023, BPOM ID EREG10000712200086-87

APA EFEK SAMPING PENTING YANG MUNGKIN TERJADI DARI PENGGUNAAN *CONVIDECIA* ?

Berdasarkan hasil uji klinik *CONVIDECIA* untuk inhalasi sebagai heterologous booster dalam dua uji klinik imunisasi heterologous booster di China, data keamanan dari uji klinis dan pengalaman penggunaan darurat vaksin Ad5-nCoV dirangkum sebagai berikut:

Efek Samping *Solicited*

(1) Efek samping lokal

Umum: mulit kering, nyeri orofaring;
Tidak umum: suara serak, pembengkakan faring, mucositis oral;
Jarang: ketidaknyamanan orofaring

(2) Efek samping sistemik

Umum: sakit kepala, kelelahan, demam, batuk, rinorea, bersin, artralgia;
Tidak umum: mual, mialgia, diare, penurunan nafsu makan, nyeri dada, gatal, muntah, gangguan mukokutan.

Efek Samping *Unsolicited***

Umum: pusing, ketidaknyamanan dada, ketidaknyamanan perut, berdahak

Tidak umum: radang gusi tidak menular, konstipasi, sakit gigi, bibir bengkak, sumbatan hidung, hidung kering, menggigil, hidrosis, tinitus, insomnia, disforia, pneumonia, infeksi saluran pernapasan atas, radang amandel, otitis media, palpitasi, peningkatan denyut jantung, frekuensi buang air kecil, disuria, hipestesia, ketidaknyamanan mata, ulkus, sesak napas.

*Efek samping *Unsolicited* dilaporkan setelah dosis booster, hingga 28 hari setelah dosis booster, pada subjek berusia di atas 18 tahun (N = 10.151), dinilai sebagai efek samping yang belum terdata pada bagian efek samping lokal dan sistemik yang *solicited*.

Tingkat keparahan efek samping

Tingkat keparahan efek samping yang diamati dalam uji klinis vaksin terutama tingkat 1 (ringan), insiden efek samping tingkat 3 dan di atasnya adalah 0,36%, terutama gejala demam, dan tidak ada efek samping dari tingkat 4 yang dilaporkan.

Kejadian tidak diinginkan yang serius

Tidak ada kejadian tidak diinginkan serius (KTDS) yang diamati dalam uji klinis.

APA PILIHAN VAKSINASI LAINNYA?

Informasi terbaru mengenai vaksin COVID-19 yang sudah mendapatkan persetujuan Emergency Use Authorization (EUA) dari Badan POM dapat dilihat di website Badan POM pada link:
https://cekbpom.pom.go.id/index.php/home/produk/31emsg6mtdmj17bidll8hq9247/all/row/10/page/1/order/4/DESC/search/5/sars-Cov-2.

APA YANG HARUS SAYA HINDARI SAAT VAKSINASI DENGAN *CONVIDECIA*?

Tidak terdapat uji klinis untuk vaksinasi bersamaan dengan vaksin lain. Namun untuk kehati-

hatian pemberian, vaksin Ad5-nCoV tidak diperbolehkan diberikan bersamaan dengan pemberian vaksin lain dalam alat inhalasi yang sama.
Tidak tersedia data yang relevan untuk penggunaan bersamaan dengan obat lain seperti imunosupresan, kemoterapi, antimetabolit, agen alkilasi, obat sitotoksik, kortikosteroid, dll., yang dapat mengurangi respons imun Ad5-nCoV.
Konsultasikan dengan dokter anda apabila anda menerima atau sedang menerima terapi obat, untuk menghindari kemungkinan interaksi obat.
Vaksin tidak boleh digunakan jika botol vial vaksin retak atau pecah, atau jika terlihat benda asing di dalam vial vaksin.

BAGAIMANA JIKA SAYA HAMIL ATAU MENYUSUI?
Data terhadap penggunaan pada ibu hamil atau menyusui terbatas dalam uji klinis. Konsultasikan dahulu dengan dokter Anda atau tenaga kesehatan lainnya bila Anda akan divaksin dan dalam keadaan hamil atau menyusui.

BAGAIMANA SAYA MELAPORKAN EFEK SAMPING VAKSINASI *CONVIDECIA*?
Hubungi dokter Anda jika Anda mengalami efek samping apapun yang dirasakan setelah penggunaan *CONVIDECIA*, laporkan efek samping ke:
Pusat Farmakovigilans
Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor Obat Narkotika, Psikotropika, Prekursor, dan Zat Adiktif
Badan Pengawas Obat dan Makanan Republik Indonesia

Melalui pos : Jl. Percetakan Negara No. 23, Jakarta Pusat,
10560 Email : pv-center@pom.go.id
Tel: +62-21-4244755 Ext. 111; 4244691 Ext. 1072
Fax: +62-21-42883485
Website: http://e-meso.pom.go.id/

BAGAIMANA PENYIMPANAN *CONVIDECIA*?
Produk ini tidak mengandung bahan pengawet. Simpan dan transportasikan dalam kondisi berpendingin pada suhu 2-8 °C sebelum digunakan.
Setelah kemasan vaksin dibuka, vaksin harus ditempatkan dalam jarum suntik tidak lebih dari 6 jam di bawah suhu kamar. Buang vaksin jika tidak digunakan dalam jangka waktu yang ditentukan.

BAGAIMANA SAYA MEMPEROLEH INFORMASI LEBIH LANJUT?
- Tanyakan pada dokter atau petugas layanan kesehatan
- Kunjungi website Badan POM : pom.go.id

KEMASAN:
Dus, 1 Vial @ 0,5 mL (3 Dosis);
Dus, 1 Vial @ 1,5 mL (14 Dosis);

HARUS DENGAN RESEP DOKTER

Diproduksi oleh :
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Tianjin - China

Diimpor dan dipasarkan oleh :
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Indonesia Jakarta - Indonesia