

**FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE
(VACCINATION PROVIDERS)**

**EMERGENCY USE AUTHORIZATION (EUA) OF
THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS
DISEASE 2019 (COVID-19)**

The Philippine Food and Drug Administration (PFDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the COVID-19 Vaccination Program must report all vaccine administration errors, all serious and non-serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine. See “MANDATORY REQUIREMENTS FOR THE JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION” for reporting requirements.

The Janssen COVID-19 Vaccine is a suspension for intramuscular injection.

Primary Vaccination

The primary vaccination regimen for the Janssen COVID-19 Vaccine is a **single-dose** (0.5 mL) administered to individuals 18 years of age and older.

Booster dose

A single Janssen COVID-19 Vaccine booster dose (0.5 mL) may be administered at least 2 months after primary vaccination with the Janssen COVID-19 Vaccine, to individuals 18 years of age and older.

A single booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see <https://vaxcheck.jnj/> or <https://www.janssencovid19vaccine.com.ph/>.

For information on clinical trials that are testing the use of the Janssen COVID-19 Vaccine for active immunization against COVID-19, please see www.clinicaltrials.gov.

DESCRIPTION OF COVID-19

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the novel coronavirus,

SARS-CoV-2, that appeared in late 2019. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have reported a wide range of symptoms, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

DOSAGE AND ADMINISTRATION

The storage and handling information in this Fact Sheet supersedes the storage and handling information on the carton and vial labels.

Storage and Handling

Storage Prior to First Puncture of the Vaccine Vial

Store unpunctured multi-dose vials of the Janssen COVID-19 Vaccine at 2°C to 8°C (36°F to 46°F) and protect from light. Do not store frozen.

Unpunctured vials of Janssen COVID-19 Vaccine may be stored between 9°C to 25°C (47°F to 77°F) for up to 12 hours.

The Janssen COVID-19 Vaccine is initially stored frozen (-25°C to -15°C) by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 4 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard the vial if vaccine is not used within these times.

Dosing and Schedule

Primary Vaccination

The primary vaccination regimen for the Janssen COVID-19 Vaccine is a single-dose (0.5 mL) administered to individuals 18 years of age and older.

Booster Dose

A single Janssen COVID-19 Vaccine booster dose (0.5 mL) may be administered at least 2 months after primary vaccination with the Janssen COVID-19 Vaccine, to individuals 18 years of age and older.

A single booster dose of the Janssen COVID-19 Vaccine (0.5 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Dose Preparation

- The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration. If either of these conditions exists, do not administer the vaccine.
- Before withdrawing each dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. **Do not shake.**
- Each dose is 0.5 mL. Each vial contains five doses. Do not pool excess vaccine from multiple vials.
- The Janssen COVID-19 Vaccine does not contain a preservative. Record the date and time of first use on the Janssen COVID-19 Vaccine vial label. After the first dose has been withdrawn, hold the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. Discard if vaccine is not used within these times.

Administration

Visually inspect each dose in the dosing syringe prior to administration. The Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains particulate matter.

Administer the Janssen COVID-19 Vaccine intramuscularly.

CONTRAINDICATIONS

Severe Allergic Reactions

Do not administer the Janssen COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine (*see Full EUA Prescribing Information*).

Thrombosis with Thrombocytopenia

Do not administer the Janssen COVID-19 Vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccines (*see Full EUA Prescribing Information*).

WARNINGS

Management of Acute Allergic Reactions

Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Janssen COVID-19 Vaccine.

Monitor Janssen COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Philippine Food and Drug Administration guidelines.

Thrombosis with Thrombocytopenia Syndrome (TTS)

Reports to the Vaccine Adverse Events Reporting System (VAERS), a passive surveillance system, provide evidence for an increased risk of thrombosis with thrombocytopenia syndrome (TTS) with onset of symptoms approximately one to two weeks after administration of the Janssen COVID-19 Vaccine. An analysis of VAERS reports of TTS following the receipt of the Janssen COVID-19 Vaccine used the following case definition:

- a thrombosis in an unusual location for a thrombus (i.e., cerebral vein, visceral artery or vein, extremity artery, central artery or vein) and new-onset thrombocytopenia (i.e., platelet count $<150,000/\mu\text{L}$) occurring any time after vaccination;
or
- new-onset thrombocytopenia (i.e., platelet count $<150,000/\mu\text{L}$), thrombosis in an extremity vein or pulmonary artery in the absence of thrombosis at an unusual location, and a positive anti-PF4 antibody ELISA test or functional Heparin-Induced Thrombocytopenia (HIT) platelet test occurring any time after vaccination.

Cases of TTS following administration of the Janssen COVID-19 Vaccine have been reported in males and females, in a wide age range of individuals 18 years and older, with the highest reporting rate (approximately 1 case per 100,000 doses administered) in females ages 30-49 years; overall, approximately 15% of TTS cases have been fatal. Currently available evidence supports a causal relationship between TTS and the Janssen COVID-19 Vaccine. The clinical course of these events shares features with autoimmune heparin-induced thrombocytopenia. In individuals with suspected TTS following administration of the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended. The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine (<https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>). (see *Full EUA Prescribing Information*).

Immune Thrombocytopenia (ITP)

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of immune thrombocytopenia (ITP) during the 42 days following vaccination. Individuals with a history of ITP should discuss with their healthcare provider the risk of ITP and the potential need for platelet monitoring following vaccination with the Janssen COVID-19 Vaccine.

Guillain-Barré Syndrome

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.

Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Janssen COVID-19 Vaccine.

Syncope

Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Limitations of Vaccine Effectiveness

The Janssen COVID-19 Vaccine may not protect all vaccinated individuals.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials

Adverse reactions reported in a clinical trial following administration of the Janssen COVID-19 Vaccine include injection site pain, headache, fatigue, myalgia, nausea, fever, injection site erythema and injection site swelling. In clinical studies, severe allergic reactions, including anaphylaxis, have been reported following the administration of the Janssen COVID-19 Vaccine (*see Full EUA Prescribing Information*).

Adverse Reactions Identified during Post Authorization Use

Anaphylaxis and other severe allergic reactions, thrombosis with thrombocytopenia, Guillain-Barré syndrome and capillary leak syndrome have been reported following administration of the Janssen COVID-19 Vaccine during mass vaccination outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Janssen COVID-19 Vaccine.

USE WITH OTHER VACCINES

There is no information on the co-administration of the Janssen COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS

As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” (and provide a copy or direct the individual to the website <https://vaxcheck.jnj/> or <https://www.janssencovid19vaccine.com.ph/> to obtain the Fact Sheet) prior to the individual receiving the Janssen COVID-19 Vaccine, including:

- PFDA has authorized the emergency use of the Janssen COVID-19 Vaccine, which is not an PFDA approved vaccine.
- The recipient or their caregiver has the option to accept or refuse the Janssen COVID-19 Vaccine.
- The significant known and potential risks and benefits of the Janssen COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Information about available alternative vaccines and the risks and benefits of those alternatives.

For information on clinical trials that are testing the use of the Janssen COVID-19 Vaccine to prevent COVID-19, please see www.clinicaltrials.gov.

Provide a vaccination card to the recipient or their caregiver with the name of the vaccine (“Janssen COVID-19 Vaccine”) and date of administration to document vaccination.

Report vaccine side effects to PFDA via Telephone no. +6328857-1900 or report online to <https://www.fda.gov.ph/covid-19-vaccine-report-a-side-effect/>.

MANDATORY REQUIREMENTS FOR JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Janssen COVID-19 Vaccine, the following items are required. Use of unapproved Janssen COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements must be met):

1. The Janssen COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.
2. The vaccination provider must communicate to the individual receiving the Janssen COVID-19 Vaccine or their caregiver, information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving the Janssen COVID-19 Vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of vaccine side effects to PFDA via Telephone. no: +632 8 857-1900 or report online to <https://www.fda.gov.ph/covid-19-vaccine-report-a-side-effect/>.
5. The vaccination provider is responsible for responding to PFDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine to recipients.

* 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;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO JOHNSON & JOHNSON (PHILIPPINES), INC.

Vaccination providers may report to PFDA via Telephone. no: +632 8 857-1900 or report online to <https://www.fda.gov.ph/covid-19-vaccine-report-a-side-effect/> other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Johnson & Johnson (Philippines), Inc. thru the contact details in <https://vaxcheck.jnj/> or <https://www.janssencovid19vaccine.com.ph/>.

ADDITIONAL INFORMATION

For general questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, visit <https://vaxcheck.jnj/> or <https://www.janssencovid19vaccine.com.ph/> or call the telephone numbers provided below:

- Toll-free number (PLDT): 1800-1110-2906
- Toll-free number (Globe): 1800-8909-4047

AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. There may be clinical trials or availability under EUA of other COVID-19 vaccines.

AUTHORITY FOR ISSUANCE OF THE EUA

The PFDA has made the Janssen COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Department of Health declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

For the definition of EUA please refer to <https://www.fda.gov.ph/fda-circular-no-2020-036-guidelines-on-the-issuance-of-emergency-use-authorization-for-drugs-and-vaccines-for-covid-19/>

The Janssen COVID-19 Vaccine has not undergone the same type of review as an PFDA-approved or cleared product. PFDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the PFDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Janssen COVID-19 Vaccine is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

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