FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine has received EUA from FDA to provide:

- A single dose primary vaccination to individuals 18 years of age and older.
- A single booster dose to individuals 18 years of age and older who have completed a primary vaccination with Janssen COVID-19 Vaccine.
- A single booster dose to eligible individuals who have completed primary vaccination with a different authorized or approved COVID-19 vaccine.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common 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.

WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?

Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies,
- have a fever,
- have a bleeding disorder or are on a blood thinner,
- are immunocompromised or are on a medicine that affects your immune system,
- are pregnant or plan to become pregnant,
- are breastfeeding,
- have received another COVID-19 vaccine,
- have ever fainted in association with an injection.

WHO SHOULD GET THE JANSSEN COVID-19 VACCINE?

FDA has authorized the emergency use of the Janssen COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine.
- had a severe allergic reaction to any ingredient of this vaccine.

WHAT ARE THE INGREDIENTS IN THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine includes the following ingredients: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate-80, sodium chloride.

HOW IS THE JANSSEN COVID -19 VACCINE GIVEN?

The Janssen COVID-19 Vaccine will be given to you as an injection into the muscle.

Primary Vaccination: The Janssen COVID-19 Vaccine is administered as a **single dose**.

Booster Dose:

- A single booster dose of the Janssen COVID-19 Vaccine may be administered at least two months after primary vaccination with the Janssen COVID-19 Vaccine.
- A single booster dose of the Janssen COVID-19 Vaccine may be administered to eligible individuals who have completed primary vaccination with a different authorized or approved COVID-19 vaccine. Please check with your health care provider regarding eligibility for and timing of the booster dose.

HAS THE JANSSEN COVID-19 VACCINE BEEN USED BEFORE?

The Janssen COVID-19 Vaccine is an unapproved vaccine. In clinical trials, more than 61,000 individuals 18 years of age and older have received the Janssen COVID-19 Vaccine. Millions of individuals have received the vaccine under EUA since February 27, 2021.

WHAT ARE THE BENEFITS OF THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine has been shown to prevent COVID-19. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

Side effects that have been reported with the Janssen COVID-19 Vaccine include:

- Injection site reactions: pain, redness of the skin and swelling.
- General side effects: headache, feeling very tired, muscle aches, nausea, and fever.
- Swollen lymph nodes.
- Blood clots.
- Unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).
- Persistent ringing in the ears (tinnitus).
- Diarrhea, vomiting.

Severe Allergic Reactions

There is a remote chance that the Janssen COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after

getting a dose of the Janssen COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing,
- Swelling of your face and throat,
- A fast heartbeat,
- A bad rash all over your body,
- Dizziness and weakness.

Blood Clots with Low Levels of Platelets

Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine. In people who developed these blood clots and low levels of platelets, symptoms began approximately one to two weeks after vaccination. Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years. The chance of having this occur is remote. You should seek medical attention right away if you have any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Shortness of breath,
- Chest pain,
- Leg swelling,
- Persistent abdominal pain,
- Severe or persistent headaches or blurred vision,
- Easy bruising or tiny blood spots under the skin beyond the site of the injection.

These may not be all the possible side effects of the Janssen COVID-19 Vaccine. Serious and unexpected effects may occur. The Janssen COVID-19 Vaccine is still being studied in clinical trials.

Guillain Barré Syndrome

Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is

very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body.
- Difficulty walking.
- Difficulty with facial movements, including speaking, chewing, or swallowing.
- Double vision or inability to move eyes.
- Difficulty with bladder control or bowel function.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Janssen COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Janssen Biotech, Inc. at the contact information provided below.

e-mail	Fax number	Telephone numbers
JNJvaccineAE@its.jnj.com	215-293-9955	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

You may also be given an option to enroll in **v-safe**. **V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE JANSSEN COVID-19 VACCINE?

It is your choice to receive or not receive the Janssen COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?

Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE JANSSEN COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Janssen COVID-19 Vaccine at the same time as other vaccines. If you are considering receiving the Janssen COVID-19 Vaccine with other vaccines, discuss your options with your healthcare provider.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE JANSSEN COVID-19 VACCINE GIVE ME COVID-19?

No. The Janssen COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD

When you receive the Janssen COVID-19 Vaccine, you will get a vaccination card to document the name of the vaccine and date of when you received the vaccine.

ADDITIONAL INFORMATION

If you have questions or to access the most recent Janssen COVID-19 Vaccine Fact Sheets, scan the QR code using your device, visit the website or call the telephone numbers provided below.

QR Code	Fact Sheets Website	Telephone numbers
	www.janssencovid19vaccine.com.	US Toll Free: 1-800-565-4008 US Toll: (908) 455-9922

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or TIPS.HHS.GOV.

WHAT IS THE COUNTERMEASURE INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses for certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made the Janssen COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Janssen COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA 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).

Manufactured by:
Janssen Biotech, Inc.
a Janssen Pharmaceutical Company of Johnson & Johnson
Horsham, PA 19044, USA

For more information, call US Toll Free: 1-800-565-4008, US Toll: (908) 455-9922 or go to www.janssencovid19vaccine.com

Revised: 10/20/2021

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

GDTI: 0886983000363

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NOTICE OF PRIVACY PRACTICES

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BEUSED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION.
PLEASE REVIEW IT CAREFULLY.

USES AND DISCLOSURES OF YOUR PROTECTED HEALTH INFORMATION

Protected health information includes demographic and medical information that concerns the past, present, or future physical or mental health of an individual. Demographic information could include your name, address, telephone number, social security number and any other means of identifying you as a specific person. Protected health information contains specific information that identifies a person or can be used to identify a person.

Protected health information is health information created or received by a health care provider, health plan, employer, or health care clearinghouse. The Department of Health can act as each of the above business types. This medical information is used by the Department of Health in many ways while performing normal business activities.

Your protected health information may be used or disclosed by the Department of Health for purposes of treatment, payment, and health care operations. *Health care professionals use medical information in the clinics or hospital to take care of you. Your protected health information may be shared, with or without your consent, with another health care provider for purposes of your treatment. The Department of Health may use or disclose your health information for case management and services. The Department of Health clinic or hospital may send the medical information to insurance companies, Medicaid, or community agencies to pay for the services provided you.*

Your information may be used by certain department personnel to improve the department's health care operations. The department also may send you appointment reminders, information about treatment options or other health-related benefits and services.

Some protected health information can be disclosed without your written authorization as allowed by law. Those circumstances include:

- Reporting abuse of children, adults, or disabled persons.
- Investigations related to a missing child.
- Internal investigations and audits by the department's divisions, bureaus, and offices.
- Investigations and audits by the state's Inspector General and Auditor General, and the legislature's Office of Program Policy Analysis and Government Accountability.
- Public health purposes, including vital statistics, disease reporting, public health surveillance, investigations, interventions, and regulation of health professionals.
- District medical examiner investigations;
- Research approved by the department.
- Court orders, warrants, or subpoenas;
- Law enforcement purposes, administrative investigations, and judicial and administrative proceedings.

Other uses and disclosures of your protected health information by the department will require your written authorization. These uses and disclosures may be for marketing and for research purposes, certain uses and disclosure of psychotherapist notes, and the sale of protected health information resulting in remuneration to the Department of Health.

This authorization will have an expiration date that can be revoked by you in writing.

INDIVIDUAL RIGHTS

You have the right to request the Department of Health to restrict the use and disclosure of your protected health information to carry out treatment, payment, or health care operations. You may also limit disclosures to individuals involved with your care. The department is notrequired to agree to any restriction.

You have the right to be assured that your information will be kept confidential. The Department of Health will make contact with you in the manner and at the address or phone number you select. You may be asked to put your request in writing. If you are responsible to pay for services, you may provide an address other than your residence where you can receive mail and where we may contact you.

You have the right to inspect and receive a copy of your protected health information that is maintained by the Department of Health within 30 days of the Department's receipt of your request.to obtain a copy of your protected health information. You must complete the Department's Authorization to Disclosure Confidential Information form and submit the request to the county health department or Children's Medical Services office. If there are delays in getting you the information, you will be told the reason for the delay and the anticipated date when you will receive your information.

Your inspection of information will be supervised at an appointed time and place. You may be denied access as specified by law.

If you choose to receive a copy of your protected health information, you have the right to receive the information in the form or format you request. If the Department cannot produce it in that form or format, it will give you the information in a readable hard copy form or another form or format that you and the Department agree to.The Department cannot give you access to psychotherapy notes or certain information being used in a legal proceeding. Records are maintained for specified periods of time in accordance with the law. If your request covers information beyond that time the Department is required to keep the record, the information may no longer be available. If access is denied, you have the right to request a review by a licensed health care professional who was not involved in the decision to deny access. This licensed health care professional will be designated by the department.

You have the right to correct your protected health information. Your request to correct your protected health information must be in writing and provide a reason to support your requested correction. The Department of Health may deny your request, in whole or part, if it finds the protected health information:

- Was not created by the department.
- Is not protected health information.
- Is by law not available for your inspection.
- Is accurate and complete.

If your correction is accepted, the department will make the correction and tell you and others who need to know about the correction. If your request is denied, you may send a letter detailing the reason you disagree with the decision. The department may respond to your letter in writing. You also may file a complaint, as described below in the section titled Complaints.

You have the right to receive a summary of certain disclosures the Department of Health may have made of your protected health information. This summary does not include:

- Disclosures made to you.
- Disclosures to individuals involved with your care.
- Disclosures authorized by you.
- Disclosures made to carry out treatment, payment, and health care operations.
- Disclosures for public health.
- Disclosures to health professional regulatory purposes.
- Disclosures to report abuse of children, adults, or disabled.
- Disclosures prior to April 14, 2003.

This summary does include disclosures made for:

- Purposes of research, other than those you authorized in writing.
- Responses to court orders, subpoenas, or warrants.

You may request a summary for not more than a 6 year period from the date of your request. If you received this Notice of Privacy Practices electronically, you have the right to a paper copy upon request.

The Department of Health may mail or call you with health care appointment reminders.

DEPARTMENT OF HEALTH DUTIES

The Department of Health is required by law to maintain the privacy of your protected health information. This Notice of Privacy Practices tells you how your protected health information may be used and how the department keeps your information private and confidential. This notice explains the legal duties and practices relating to your protected health information. The department has the responsibility to notify you following a breach of your unsecured protected health information.

As part of the department's legal duties this Notice of Privacy Practices must be given to you. The department is required to follow the terms of the Notice of Privacy Practices currently in effect.

The Department of Health may change the terms of its notice. The change, if made, will be effective for all protected health information that it maintains. New or revised notices of privacy practices will be posted on the Department of Health website at http://www.floridahealth.gov/about-the-department-of-health/about-us/patient-rights-and- safety/hipaa/index.html and will be available by email and at all Department of Health buildings. Also available are additional documents that further explain your rights to inspect and copy and amend your protected health information.

COMPLAINTS

If you believe your privacy health rights have been violated, you may file a complaint with the: Department of Health's Inspector General at 4052 Bald Cypress Way, BIN A03/ Tallahassee, FL 32399-1704/ telephone 850-245-4141 and with the Secretary of the U.S. Department of Health and Human Services at 200 Independence Avenue, S.W./ Washington, D.C. 20201/ telephone 202-619-0257 or toll free 877-696-6775.

The complaint must be in writing, describe the acts or omissions that you believe violate your privacy rights, and be filed within 180 days of when you knew or should have known that the act or omission occurred. The Department of Health will not retaliate against you for filing a complaint.

FOR FURTHER INFORMATION

Requests for further information about the matters covered by this notice may be directed to the person who gave you the notice, to the director or administrator of the Department of Health facility where you received the notice, or to the Department of Health's Inspector General at 4052 Bald Cypress Way, BIN A03/ Tallahassee, FL 32399-1704/ telephone 850-245-4141.

EFFECTIVE DATE

This Notice of Privacy Practices is effective beginning July 1, 2013, and shall be in effect until a new Notice of Privacy Practices is approved and posted.

REFERENCES

"Standards for the Privacy of Individually Identifiable Health Information; Final Rule." 45 CFR Parts 160 through 164. *Federal Register* 65, no. 250 (December 28, 2000).
"Standards for the Privacy of Individually Identifiable Health Information; Final Rule" 45 CFR Part 160 through 164. *Federal Register*, Volume 67 (August 14, 2002).

HHS, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information and Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566 (Jan. 25, 2013).