



SCL Health Combined EUA Fact Sheet for Recipients and Caregivers for Moderna, Pfizer and Janssen COVID-19 Vaccine. This combined fact sheet is provided for informational purposes only and does not replace the vaccine-specific EUA fact sheet which will be provided to the recipient or caregiver at the time of vaccination based upon the vaccine being administered.

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

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

OR

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

OR

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 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 COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

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

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle. The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle. The Janssen COVID-19 Vaccine is administered as a single dose, into the muscle.

The COVID-19 Vaccine may not protect everyone.

These Fact Sheets may have been updated. For the most recent Moderna Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua. For the most recent Pfizer-BioNTech Fact Sheet, please visit www.cvdvaccine.com. For the most recent Janssen Fact Sheet, please visit

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 COVID-19 VACCINE?

The COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older (Moderna & Janssen) OR 16 years of age and older (Pfizer) 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 COVID-19 VACCINE?

Tell your 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

WHO SHOULD GET THE COVID-19 VACCINE?

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

FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

WHO SHOULD NOT GET THE COVID-19 VACCINE?

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

- had a severe allergic reaction to any ingredient of this vaccine
- had a severe allergic reaction after a previous dose of this vaccine ([Moderna](#) or [Pfizer](#))

WHAT ARE THE INGREDIENTS IN THE COVID-19 VACCINE?

The [Moderna](#) COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

The [Pfizer-BioNTech](#) COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

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 COVID-19 VACCINE GIVEN?

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

The [Moderna](#) COVID-19 Vaccine vaccination series is 2 doses given 1 month apart. If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

The [Pfizer-BioNTech](#) COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart. If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

The Janssen COVID-19 Vaccine vaccination schedule is a single dose.

HAS THE COVID-19 VACCINE BEEN USED BEFORE?

The COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the [Moderna](#) COVID-19 Vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the [Pfizer-BioNTech](#) COVID-19 Vaccine. In an ongoing clinical trial, 21,895 individuals 18 years of age and older have received the [Janssen](#) COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE COVID-19 VACCINE?

In an ongoing clinical trial, the [Moderna](#) COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. In an ongoing clinical trial, the [Pfizer-BioNTech](#) COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. In an ongoing clinical trial, the [Janssen](#) COVID-19 Vaccine has been

shown to prevent COVID-19 following a single dose. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE COVID-19 VACCINE?

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

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

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

- Injection site pain
- Tiredness
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Injection site swelling
- Injection site redness
- Nausea
- Feeling unwell
- Swollen lymph nodes (lymphadenopathy)

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

There is a remote chance that the 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 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

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

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 “Moderna COVID-19 Vaccine EUA” or “Pfizer-BioNTech COVID-19 Vaccine EUA” or “Janssen COVID-19 Vaccine EUA” in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762) if you received the Moderna COVID-19 vaccine. You can report side effects to Pfizer Inc. at www.pfizersafetyreporting.com, fax: 1-866-635-8337, phone: 1-800-438-1985. You can report side effects to Janssen Biotech, Inc at JNJvaccineAE@its.jnj.com, fax: 215-293-9955, phone: US Toll Free: 1-800-565-4008 or 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 second-dose reminders if needed and 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 COVID-19 VACCINE?

It is your choice to receive or not receive the 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 MODERNA, PFIZER-BIONTECH OR JANSSEN COVID-19 VACCINE?

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Moderna, Pfizer-BioNTech and Janssen COVID-19 vaccines are currently available under Emergency Use Authorization. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE COVID-19 VACCINE WITH OTHER VACCINES?

There is no information on the use of the COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

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

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

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


KEEP YOUR VACCINATION CARD

When you receive your first dose (Moderna or Pfizer) or your Janssen vaccine, you will get a vaccination card to show you when to return for your second dose (Moderna or Pfizer) of the COVID-19 Vaccine and to document the name of the vaccine and date of when you received the vaccine.. Remember to bring your card when you return for your second dose (Moderna or Pfizer).


ADDITIONAL INFORMATION

If you have questions, visit the appropriate website or call the telephone number provided below. To access the most recent Fact Sheets, please scan the QR code provided below.


Moderna:

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

Pfizer:

Global website	Telephone number
www.cvdvaccine.com 	1-877-829-2619 (1-877-VAX-CO19)

Janssen:

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-legalregulatory-and-policy-framework/emergency-use-authorization>
- Contact your state or local 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. If needed, this will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

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

Moderna COVID-19 Vaccine: ©2020 ModernaTX, Inc. All rights reserved. Patent(s): www.modernatx.com/patents

Pfizer-BioNTech COVID-19 Vaccine: Manufactured by Pfizer Inc., New York, NY 10017
Manufactured for BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz, Germany
LAB-1451-1.0

Janssen COVID-19 Vaccine: Manufactured by: Janssen Biotech, Inc. A Janssen Pharmaceutical Company of Johnson & Johnson. Horsham, PA 19044, USA

Updated: February 28, 2021

Includes all information contained in the Fact Sheet for Recipients and Caregivers for the Moderna, Pfizer-BioNTech & Janssen COVID-19 vaccine.

References:

1. Fact sheet for recipients and caregivers: emergency use authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). US Food and Drug Administration (FDA). Published: December 11, 2020.
<https://www.cvdvaccine-us.com/images/pdf/fact-sheet-for-recipients-and-caregivers.pdf>
2. Fact sheet for recipients and caregivers: emergency use authorization (EUA) of The Moderna COVID-19 Vaccine. US Food and Drug Administration (FDA). Published: December 11, 2020.
<https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf>
3. Fact sheet for recipients and caregivers: emergency use authorization (EUA) of The Janssen COVID-19 Vaccine. US Food and Drug Administration (FDA). Published: February 27, 2021.
<https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-Recipient-fact-sheet.pdf>