Lawrence Nursing Care Center, Inc
350 Beach 54th Street
Arverne, New York 11692
Voice: 718-945-0400 Facsimile: 718-945-5954

December 22, 2021

Dear Family Members/Designated Representatives:

I hope this letter finds you well and you are enjoying the Holiday Season. I am sure that you are aware that Nursing Home Patients/Resident and staff will be among the first to receive the COVID-19 Vaccine in New York State. Lawrence Nursing Care Center has partnered with CVS for vaccine administration storage and data reporting. We are strongly encouraging ALL of our patients and residents to be vaccinated. We have screening questionnaire to determine eligibility and consent forms attached to the letter. We are also encouraging ALL of our Staff to be vaccinated.

This will be done in a systematic way in coordination with CVS and in compliance with all NYSDOH and Centers for Disease Control recommendations and guidelines. As of now, we expect verbal consents for the vaccine to be permissible. I encourage everyone to do their own research ahead of time and make a decision. We plan to start vaccinating our residents in January 2021. Please be careful when googling information on the vaccine as there are a lot of misinformation on the internet. We are also posting the information on the vaccine on our website. If you do not wish your loved one to get vaccinated, please inform your loved one's social worker or unit manager. Attached are the consent forms and COVID-19 Vaccine information, kindly return the consent form or refusal as soon as possible.
Upon receipt of this letter, please contact the social worker and or the Director of Nursing.

718-945-0400 extension 168 or Ext. 125.

Thank you for your cooperation and promptness in handling this matter. If you have any questions, please do not hesitate to speak to your loved one's primary care physician at the facility.

Best Regards,

Margaret Alade R.N., MS. LNHA
Administrator.

NEW YORK STATE OF OPPORTUNITY. | Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

Information for Healthcare Professionals about the Screening Checklist for the COVID-19 Vaccine*

NOTE: For summary information on contraindications an precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html

* This form is current as of December 13, 2020. Please consult ACIP, FDA and relevant manufacturer's websites for the most current clinical updates including, but not limited to: ACIP at www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html and FDA at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine.

1. **Are you feeling sick today?**

   If yes, refer to the vaccination site healthcare provider for assessment of current health status. If patient is feeling moderately or severely ill, do not vaccinate at this time and ask the patient to return when symptoms improve.

2. In the last 10 days have you had a COVID-19 test or been told by a healthcare provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure? Are you on quarantine because of travel requirements?

   If yes, advise patient to return to isolation/quarantine, and reschedule for after isolation or quarantine ends.

   If patient was diagnosed with COVID-19 greater than 10 days ago and has been asymptomatic for 24 hours or more, patient may be vaccinated.

   If the patient has had a test in the last 10 days, ask the result. If positive send them home, if negative they can proceed to vaccination. If the result is unsure or unknown advise the patient to return once a negative test has been confirmed or 10 days have passed since a positive test.

3. Have you been treated with antibody therapy for COVID-19 in the past 90 days (3 months)? If yes, when did you receive the last dose?

   If yes, reschedule at least 90 days after last dose of antibody therapy.

4. Have you ever had a serious or life-threatening allergic reaction, such as hives or difficulty breathing, to any vaccine or shot?

   If yes, then refer to the vaccination site healthcare provider for assessment of allergic reaction.

5. Have you had any vaccines in the past 14 days (2 weeks) including flu shot? If yes, how long ago was your most recent vaccine?

   If yes, then reschedule at least 14 days after the most recent vaccine.

6. Are you pregnant or considering becoming pregnant?

   If yes, ask the patient to consider having a discussion with her/their provider or a healthcare provider at site for counseling on the risks and benefits of COVID-19 vaccine during pregnancy.

   Patient may be vaccinated if they choose.

7. **Do you have cancer, leukemia, HIV/AIDS, a history of autoimmune disease or any other condition that weakens the immune system?**

   If yes, refer to the vaccination site healthcare provider to discuss what is known and not yet known about COVID-19 vaccine for immunocompromised people.

   You can tell the patient that if they are immunocompromised or are on a medicine that affects their immune system, they may have a less strong immune response to the vaccine but may still get vaccinated. They should continue to follow current guidance to protect themselves against COVID-19.

8. **Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments recently?**

   If yes, refer to healthcare provider to discuss what is known and not yet known about COVID-19 vaccine for immunosuppressed people.

   You can tell the patient that if they are immunocompromised or are on a medicine that affects their immune system, they may have a less strong immune response to the vaccine but may still get vaccinated. They should continue to follow current guidance to protect themselves against COVID-19.

*** Anyone answering "Unknown" to any screening question should be referred to the medical director or responsible healthcare provider at the POD or clinic to further assess their answer to that question. (E.g., the person might not have understood the question and the healthcare provider could explain it further).**

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

COVID-19 Immunization Screening and Consent Form*

Recipient Name (please print)			Preferred Name	
DOB	Legal Gender	Gender ID	Marital Status	**Marital Status Key:** S – Single D – Divorced M – Married W – Widowed V – Civil Union U – Unknown SEPARATED – Legally Separated PARTNER – Life Partner
Address City State Zip				Email Address
Parent/Guardian/ Surrogate (if applicable, please print)			Phone	Preferred Language
Ethnicity **Ethnicity Key:** DECL – Declined HIS – Hispanic Origin NHL – Non-Hispanic Origin UNK - Unknown			Race **Race Key:** AIA – Native American or Alaskan ASN – Asian BAA – African American or Black DECL – Declined NHP – Native Hawaiian or Pacific Islander WHT – White OTH – Other or Multiracial	
Clinic/Office Site Where Vaccine is Administered			Primary Care Physician Address/Phone Number	

	Screening Questionnaire			
1.	Are you feeling sick today?	☐ Yes	☐ No	
2.	In the last 10 days, have you had a COVID-19 test or been told by a healthcare provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure?	☐ Yes	☐ No	☐ Unknown
3.	Have you been treated with antibody therapy for COVID-19 in the past 90 days (3 months)? *If yes, when did you receive the last dose?*	☐ Yes	☐ No	☐ Unknown
4.	Have you ever had a serious or life-threatening allergic reaction, such as hives or difficulty breathing, to any vaccine or shot?	☐ Yes	☐ No	☐ Unknown
5.	Have you had any vaccines in the past 14 days (2 weeks) including flu shot+? *If yes, how long ago was your most recent vaccine?*	☐ Yes	☐ No	☐ Unknown
6.	Are you pregnant or considering becoming pregnant?	☐ Yes	☐ No	☐ Unknown
7.	Do you have cancer, leukemia, HIV/AIDS, a history of autoimmune disease or any other condition that weakens the immune system?	☐ Yes	☐ No	☐ Unknown
8.	Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments?	☐ Yes	☐ No	☐ Unknown

Emergency Use Authorization

The FDA has made the COVID-19 vaccine available under an emergency use authorization (EUA). The EUA is used when circumstances exist to justify the emergency use of drugs and biological products during an emergency, such as the COVID-19 pandemic. This vaccine has not completed the same type of review as an FDA-approved or cleared product. However, the FDA's decision to make the vaccine available under an EUA is based on the existence of a public health emergency and the totality of scientific evidence available, showing that known and potential benefits of the vaccine outweigh the known and potential risks.

December 2020

Consent

I have been provided and have read, or had explained to me, the information sheet about the COVID-19 vaccination. I understand that if this vaccine requires two doses, two doses of this vaccine will need to be administered (given) in order for it to be effective. I have been given an opportunity to ask questions which were answered to my satisfaction (and ensured the person named above for whom I am authorized to provide surrogate consent was also given a chance to ask questions). I understand the benefits and risks of the vaccination as described.

I request that the COVID-19 vaccination be given to me (or the person named above for whom I am authorized to make this request and provide surrogate consent). I understand there will be no cost to me for this vaccine. I understand that any monies or benefits for administering the vaccine will be assigned and transferred to the vaccinating provider, including benefits/monies from my health insurance plan, Medicare, Medicaid or other third parties who are financially responsible for my medical care. I authorize release of all information needed (including but not limited to medical records, copies of claims and itemized bills) to verify payment and as needed for other public health purposes, including reporting to applicable vaccine registries.

Recipient/Surrogate/Guardian (Signature)	Date / Time	Print Name	Relationship to patient, if other than recipient

Telephonic Interpreter's ID# **OR**	Date / Time

Signature: Interpreter	Date/ Time	Print: Interpreter's Name and Relationship to Patient

Area Below to be Completed by Vaccinator				
Which vaccine is the patient receiving today?				
Vaccine Name	Administration		EUA Fact Sheet Date	Manufacturer & Lot Number
Pfizer/ BioNTech	☐ First Dose	☐ Second Dose		
Moderna	☐ First Dose	☐ Second Dose		
Astra-Zeneca	☐ First Dose	☐ Second Dose		
Janssen	☐ Single Dose			

Administration Site ☐ Left Deltoid ☐ Right Deltoid ☐ Left Thigh ☐ Right Thigh ☐ Nasal

Dosage ☐ 0.5 ml ☐ 0.25ml

☐ I have reviewed side effects with patient (and parent, guardian or surrogate, as applicable)

☐ I confirm that the patient (and their surrogate, if applicable) was given an opportunity to ask questions about the vaccination, and all the questions asked by them (and/or their surrogate) have been answered correctly and to the best of my ability.

Vaccinator Signature: _____

*** Use of this form is optional.**

December 2020

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

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

You are being offered the Pfizer-BioNTech 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 the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

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

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

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

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE?

WHAT IS COVID-19?

COVID-19 disease 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. 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 PFIZER-BIONTECH COVID-19 VACCINE?

The Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 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 PFIZER-BIONTECH 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

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?

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

WHO SHOULD <u>NOT</u> GET THE PFIZER-BIONTECH COVID-19 VACCINE?

You should not get the Pfizer-BioNTech 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 PFIZER-BIONTECH COVID-19 VACCINE?

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.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?

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

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.

HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?

The Pfizer-BioNTech COVID-19 Vaccine is an unapproved 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.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

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. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?

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)

There is a remote chance that the Pfizer-BioNTech 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 Pfizer-BioNTech COVID-19 Vaccine. 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 Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech 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 "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

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

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?
It is your choice to receive or not receive the Pfizer-BioNTech 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 PFIZER-BIONTECH COVID-19 VACCINE?
Currently, there is no approved alternative vaccine available for prevention of COVID-19. FDA may allow the emergency use of other vaccines to prevent COVID-19.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Pfizer-BioNTech 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 PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?
No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

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

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. 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 Pfizer-BioNTech 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 Pfizer-BioNTech 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, 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 in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech 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).

Manufactured by
Pfizer Inc., New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-0.7

Revised: December 2020

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

Barcode Date: 12/2020

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

You are being offered the Moderna 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 the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna 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 Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

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. 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 MODERNA COVID-19 VACCINE?
The Moderna 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 Moderna 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 MODERNA 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 MODERNA COVID-19 VACCINE?

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

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna 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 MODERNA 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.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna 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.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna 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.

WHAT ARE THE BENEFITS OF THE MODERNA 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. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE MODERNA 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

There is a remote chance that the Moderna 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 Moderna 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 Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna 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" 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).

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 MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna 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 COVID-19 VACCINE?
Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna 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 MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna 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, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

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

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 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. 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 Moderna 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 Moderna 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 Moderna 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).

Patent(s): www.modernatx.com/patents
Revised: 12/2020

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

Barcode Date: 12/2020