FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT MODERNA COVID-19 VACCINE (2023-2024 FORMULA) WHICH HAS EMERGENCY USE AUTHORIZATION (EUA) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 6 MONTHS THROUGH 11 YEARS OF AGE

Your child is being offered Moderna COVID-19 Vaccine (2023-2023 Formula)[1] to prevent coronavirus disease 2019 (COVID-19), which is caused by the virus SARS-CoV-2. This fact sheet contains information to help you understand the risks and benefits of Moderna COVID-19 Vaccine (2023-2024 Formula), hereafter referred to as Moderna COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

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

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make Moderna COVID-19 Vaccine available during the COVID-19 pandemic (for more details about an EUA please see "**What is an Emergency Use Authorization?**" at the end of this document). Moderna COVID-19 Vaccine is not an FDA-approved vaccine for ages 6 months through 11 years of age in the United States. Read this Fact Sheet for information about Moderna COVID-19 Vaccine.

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through close 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 leading to death. 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 MODERNA COVID-19 VACCINE?

Moderna COVID-19 Vaccine is a vaccine for use in individuals 6 months through 11 years of age to prevent COVID-19. The FDA has authorized the emergency use of Moderna COVID-19 Vaccine under an EUA.

Moderna COVID-19 Vaccine may not protect everyone.

[1] Moderna COVID-19 Vaccine (2023-2024 Formula) encodes the spike protein of the Omicron XBB.1.5 SARS-CoV-2.

WHAT SHOULD YOU MENTION TO THE VACCCINATION PROVIDER BEFORE YOUR CHILD GETS MODERNA COVID-19 VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects your child's immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

Moderna COVID-19 Vaccine is given as an injection into the muscle.

Individuals 6 months through 4 years of age:

- **Unvaccinated individuals:** Two doses of Moderna COVID-19 Vaccine are administered. The second dose is administered 1 month after the first.
- **Individuals who have received one dose of Moderna COVID-19 Vaccine (Original monovalent)[2] or Moderna COVID-19 Vaccine, Bivalent:[3]** A single dose of Moderna COVID-19 Vaccine is administered 1 month after Moderna COVID-19 Vaccine (Original monovalent) or Moderna COVID-19 Vaccine, Bivalent.
- **Individuals who have received two or more doses of Moderna COVID-19 Vaccine (Original monovalent) or Moderna COVID-19 Vaccine, Bivalent:** A single dose of Moderna COVID-19 Vaccine is administered at least 2 months after the last previous dose of Moderna COVID-19 Vaccine (Original monovalent) or Moderna COVID-19 Vaccine, Bivalent.

Individuals 5 years through 11 years of age:

- **Unvaccinated individuals:** A single dose of Moderna COVID-19 Vaccine.
- **Individuals who have received one or more doses of a monovalent COVID-19 vaccine[4] or a bivalent COVID-19 vaccine:[5]** A single dose of Moderna COVID-19 Vaccine is administered at least 2 months after the last previous dose of any monovalent COVID-19 vaccine or bivalent COVID-19 vaccine.

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[2] Original monovalent Moderna COVID-19 Vaccine encodes the spike protein of only the Original SARS-CoV-2, no longer authorized for use in the U.S.

[3] Moderna COVID-19 Vaccine, Bivalent encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2, no longer authorized for use in the U.S.

[4] Monovalent refers to a COVID-19 vaccine that encodes the spike protein of only the Original SARS-CoV-2.

[5] Bivalent refers to a COVID-19 vaccine that encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2.

Immunocompromised individuals 6 months through 11 years of age:
Additional doses of Moderna COVID-19 Vaccine may be administered. For more information, talk to your child's healthcare provider.

WHO SHOULD NOT GET MODERNA COVID-19 VACCINE?

Your child should not get Moderna COVID-19 Vaccine if your child had:

- a severe allergic reaction after a previous dose of any Moderna COVID-19 vaccine.
- a severe allergic reaction to any ingredient in these vaccines.

WHAT ARE THE INGREDIENTS IN THIS VACCINE?

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 trihydrate, and sucrose.

HAS THIS VACCINE BEEN USED BEFORE?

Millions of individuals 6 months of age and older have received a Moderna COVID-19 vaccine under EUA. In clinical trials, approximately 5,000 individuals 6 months through 5 years of age, 4,000 individuals 6 years through 11 years of age, and 30,000 individuals 12 years of age and older have received at least 1 dose of Moderna COVID-19 Vaccine (Original monovalent).

The Moderna COVID-19 Vaccine is made in the same way as the Moderna COVID-19 Vaccine (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

WHAT ARE THE BENEFITS OF MODERNA COVID-19 VACCINE?

FDA has authorized Moderna COVID-19 Vaccine to provide protection against COVID-19.

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

WHAT ARE THE RISKS OF MODERNA COVID-19 VACCINE?

There is a remote chance that the 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. For this reason, the vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines. Myocarditis and pericarditis following Moderna COVID-19 vaccines have occurred most commonly in young adult males 18 years through 24 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very

low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after your child receives a dose of the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

Side effects that have been reported in clinical trials with Moderna COVID-19 vaccines include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection or in the groin, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, fever, rash, irritability/crying, sleepiness, and loss of appetite

Side effects that have been reported during post-authorization use include:

- Severe allergic reactions
- Urticaria (itchy rash/hives)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all the possible side effects. Serious and unexpected side effects may occur. The possible side effects are still being studied.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child 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 (2023-2024 Formula) 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).

WHAT IF I DECIDE NOT TO HAVE MY CHILD GET MODERNA COVID-19 VACCINE?
Under the EUA, there is an option to accept or refuse receiving this vaccine. Should you decide for your child not to receive this vaccine, it will not change the standard medical care.

ARE THERE OTHER VACCINES FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under EUA, including vaccines that encode the spike protein of the SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

CAN MY CHILD RECEIVE MODERNA COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not yet been submitted to FDA on administration of Moderna COVID-19 Vaccine at the same time as other vaccines. If you are considering having your child receive Moderna COVID-19 Vaccine with other vaccines, discuss your options with your child's healthcare provider.

WHAT IF MY CHILD IS IMMUNOCOMPROMISED?
Immunocompromised individuals 6 months through 11 years of age may receive additional doses of Moderna COVID-19 Vaccine (see **HOW IS THE VACCINE GIVEN?** above).

Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised; therefore, your child should continue to maintain physical precautions to help prevent COVID-19. Your child's close contacts should be vaccinated as appropriate.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?
If your child is pregnant or breastfeeding, discuss the options with your child's healthcare provider.

WILL THIS VACCINE GIVE MY CHILD COVID-19?
No. This vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.

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 VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your child's 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.

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 FDA has made Moderna COVID-19 Vaccine available under an emergency access mechanism call an EUA. An 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. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA-approved 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 under EUA during the COVID-19 pandemic.

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

Moderna US, Inc.
Princeton, NJ 08540

Patent(s): www.modernatx.com/patents
Revised: September/11/2023

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

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FACT SHEET FOR RECIPIENTS AND CAREGIVERS ABOUT PFIZER-BIONTECH COVID-19 VACCINE (2023-2024 FORMULA) WHICH HAS EMERGENCY USE AUTHORIZATION (EUA) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 6 MONTHS THROUGH 11 YEARS OF AGE

Your child is being offered the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) to prevent coronavirus disease 2019 (COVID-19), which is caused by the virus SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula), hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine, which your child may receive because there is currently a pandemic of COVID-19. Talk to your child's vaccination provider if you have questions.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see https://www.covidvaxoption.com/.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make the Pfizer-BioNTech COVID-19 Vaccine available during the COVID-19 pandemic (for more details about an EUA please see "**WHAT IS AN EMERGENCY USE AUTHORIZATION?**" at the end of this document). The Pfizer-BioNTech COVID-19 Vaccine is not an FDA-approved vaccine in the United States. Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine.

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. You can get COVID-19 through close 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 leading to death. 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 a vaccine for use in individuals 6 months through 11 years of age to prevent COVID-19[1]. The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine under an EUA.

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

[1] The Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

WHAT SHOULD YOU MENTION TO THE VACCINATION PROVIDER BEFORE YOUR CHILD GETS THE PFIZER-BIONTECH COVID-19 VACCINE?

Tell the vaccination provider about all of your child's medical conditions, including if your child:

- has any allergies
- has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- has a fever
- has a bleeding disorder or is on a blood thinner
- is immunocompromised or is on a medicine that affects the immune system
- is pregnant
- is breastfeeding
- has received another COVID-19 vaccine
- has ever fainted in association with an injection

HOW IS THE VACCINE GIVEN?

The Pfizer-BioNTech COVID-19 Vaccine is given as an injection into the muscle.

Individuals 6 months through 4 years of age

- **Unvaccinated individuals:** Three doses of Pfizer-BioNTech COVID-19 Vaccine are administered over at least 11 weeks. The first 2 doses are administered 3 weeks apart. The third dose is administered at least 8 weeks after the second dose.
- **Individuals who have received 1 dose of the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent)[2] or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent[3]:** Two doses of Pfizer-BioNTech COVID-19 Vaccine are administered. The first dose of Pfizer-BioNTech COVID-19 Vaccine is administered 3 weeks after the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent and the second dose at least 8 weeks later.
- **Individuals who have received 2 to 4 doses of the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) or the Pfizer BioNTech COVID-19 Vaccine, Bivalent:** A single dose of Pfizer-BioNTech COVID-19 Vaccine is administered at least 8 weeks after the last previous dose of Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) or the Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

[2] The Original monovalent Pfizer-BioNTech COVID-19 Vaccine encodes the spike protein of only the Original SARS-CoV-2, no longer authorized for use in the U.S.

[3] The Pfizer-BioNTech COVID-19 Vaccine, Bivalent encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2, no longer authorized for use in the U.S.

Individuals 5 through 11 years of age

- **Unvaccinated individuals:** A single dose of Pfizer-BioNTech COVID-19 Vaccine.
- **Individuals who have received 1 or more doses of a monovalent COVID-19 vaccine[4] or a bivalent COVID-19 vaccine[5]:** A single dose of Pfizer-BioNTech COVID-19 Vaccine is administered at least 2 months after the last previous dose of any monovalent COVID-19 vaccine or bivalent COVID-19 vaccine.

Immunocompromised individuals 6 months through 11 years of age

Additional doses of Pfizer-BioNTech COVID-19 Vaccine may be administered. For more information, talk to your child's healthcare provider.

WHO SHOULD NOT GET PFIZER-BIONTECH COVID-19 VACCINE?

A person should not get Pfizer-BioNTech COVID-19 Vaccine if they had:

- a severe allergic reaction after a previous dose of any Pfizer-BioNTech COVID-19 vaccine
- a severe allergic reaction to any ingredient in these vaccines.

WHAT ARE THE INGREDIENTS IN THIS VACCINE?

Pfizer-BioNTech COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (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), tromethamine, tromethamine hydrochloride, and sucrose. Pfizer-BioNTech COVID-19 Vaccine may also contain sodium chloride.

HAS THIS VACCINE BEEN USED BEFORE?

Millions of individuals 6 months of age and older have received a Pfizer-BioNTech COVID-19 vaccine under EUA.

In a clinical trial, approximately 1,200 individuals 6 months through 23 months of age, approximately 1,800 individuals 2 through 4 years of age, and approximately 3,100 individuals 5 through 11 years of age have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent). In another clinical trial, approximately 23,000 individuals 12 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent).

In clinical trials, 60 individuals 6 months through 4 years of age, 113 individuals 5 through 11 years of age, 107 individuals 12 through 17 years of age, 103 individuals 18 through 55 years of age, and 106 individuals greater than 55 years of age received a dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent.

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[4] Monovalent refers to a COVID-19 vaccine that encodes the spike protein of only the Original SARS-CoV-2.

[5] Bivalent refers to a COVID-19 vaccine that encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2.

The Pfizer-BioNTech COVID-19 Vaccine is made in the same way as the Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

WHAT ARE THE BENEFITS OF PFIZER-BIONTECH COVID-19 VACCINE?
FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine to provide protection against COVID-19.

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

WHAT ARE THE RISKS OF PFIZER-BIONTECH COVID-19 VACCINE?
There is a remote chance that the 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. For this reason, the vaccination provider may ask your child to stay at the place where your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines. Myocarditis and pericarditis following Pfizer-BioNTech COVID-19 vaccines have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after your child receives a dose of the vaccine:

- Chest pain
- Shortness of breath or difficulty breathing
- Feelings of having a fast-beating, fluttering, or pounding heart

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin

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

- Severe allergic reactions
- Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site pain/tenderness
- Tiredness
- Headache
- Muscle pain
- Chills
- Joint pain
- Fever
- Injection site swelling
- Injection site redness
- Nausea
- Feeling unwell
- Swollen lymph nodes (lymphadenopathy)
- Decreased appetite
- Diarrhea
- Vomiting
- Arm pain
- Fainting in association with injection of the vaccine
- Dizziness
- Irritability

These may not be all the possible side effects. Serious and unexpected side effects may occur. The possible side effects are still being studied.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your child's healthcare provider if your child has any side effects that bother your child 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 (2023-2024 Formula) 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 HAVE MY CHILD GET THE PFIZER-BIONTECH COVID-19 VACCINE?
Under the EUA, there is an option to accept or refuse receiving this vaccine. Should you decide for your child not to receive this vaccine, it will not change the standard medical care.

ARE THERE OTHER VACCINES FOR PREVENTING COVID-19 BESIDES THE PFIZER-BIONTECH COVID-19 VACCINE?
Other vaccines to prevent COVID-19 may be available under EUA, including vaccines that encode the spike protein of the SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

CAN MY CHILD RECEIVE PFIZER-BIONTECH COVID-19 VACCINE AT THE SAME TIME AS OTHER VACCINES?
Data have not been submitted to FDA on administration of Pfizer-BioNTech COVID-19 Vaccine at the same time as other vaccines. If you are considering having your child receive Pfizer-BioNTech COVID-19 Vaccine with other vaccines, discuss the options with your child's healthcare provider.

WHAT IF MY CHILD IS IMMUNOCOMPROMISED?
Immunocompromised individuals 6 months through 11 years of age may receive additional doses of Pfizer-BioNTech COVID-19 Vaccine (see **HOW IS THE VACCINE GIVEN?** above).

Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised; therefore, your child should continue to maintain physical precautions to help prevent COVID-19. Your child's close contacts should be vaccinated as appropriate.

WHAT ABOUT PREGNANCY OR BREASTFEEDING?
If your child is pregnant or breastfeeding, discuss the options with your child's healthcare provider.

WILL THIS VACCINE GIVE MY CHILD COVID-19?
No. This vaccine does not contain SARS-CoV-2 and cannot give your child COVID-19.

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 VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your child's 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.

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 FDA has made Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. An 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. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA-approved 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 under EUA during the COVID-19 pandemic.

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

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

Pfizer
Manufactured by
Pfizer Inc., New York, NY 10001

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GDTI: *0886983000585*

Information for Recipients and Caregivers
SPIKEVAX (pronounced SPĪK-văx)
(COVID-19 Vaccine, mRNA)
(2023-2024 Formula)

Please read this information sheet before getting SPIKEVAX. This summary is not intended to take the place of talking with your healthcare provider. If you have questions or would like more information, please talk with your healthcare provider.

What is SPIKEVAX?

SPIKEVAX is a vaccine to protect you against COVID-19. SPIKEVAX is for people 12 years of age and older. Vaccination with SPIKEVAX may not protect all people who receive the vaccine.

SPIKEVAX does not contain SARS-CoV-2, the virus that causes COVID-19. SPIKEVAX cannot give you COVID-19.

Who should not get SPIKEVAX?

You should not get SPIKEVAX if you had:

- a severe allergic reaction after a previous dose of SPIKEVAX, Moderna COVID-19 Vaccine (Original monovalent), or Moderna COVID-19 Vaccine, Bivalent[1]
- a severe allergic reaction to any ingredient of this vaccine (see **What are the ingredients in SPIKEVAX?**)

What should I tell my healthcare provider?

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

- have any allergies
- had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- 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 any other COVID-19 vaccine
- have ever fainted in association with an injection

How is SPIKEVAX given?

SPIKEVAX is given as an injection into the muscle.

What are the risks of SPIKEVAX?

Severe allergic reactions have occurred in some people who have received SPIKEVAX,

[1] SPIKEVAX is made the same way as the Moderna COVID-19 Vaccine (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent, but it encodes the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

Moderna COVID-19 Vaccine (Original monovalent), and Moderna COVID-19 Vaccine, Bivalent. There is a very small chance that SPIKEVAX could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose of SPIKEVAX. For this reason, your healthcare provider may ask you to stay for a short time at the place where you received your vaccine. Signs of a severe allergic reaction can include:

- Trouble breathing
- Swelling of your face and throat
- A fast heartbeat
- A rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines, including SPIKEVAX, Moderna COVID-19 Vaccine (Original monovalent), and Moderna COVID-19 Vaccine, Bivalent. Myocarditis and pericarditis following Moderna COVID-19 vaccines have occurred, most commonly in males 18 years through 24 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if you or your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported in clinical trials with SPIKEVAX, Moderna COVID-19 Vaccine (Original monovalent), and Moderna COVID-19 Vaccine, Bivalent 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, fever, and rash

Other side effects that have been reported include:

- Severe allergic reactions
- Urticaria (itchy rash/hives)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Fainting in association with injection of the vaccine

These may not be all of the possible side effects of SPIKEVAX. Ask your healthcare provider about any side effects that concern you. You may report side effects to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or https://vaers.hhs.gov.

What if I am pregnant or breastfeeding?

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

A pregnancy exposure registry is available. You are encouraged to contact the registry as soon as

you become aware of your pregnancy by calling 1-866-MODERNA (1-866-663-3762) or ask your healthcare provider to contact the registry for you.

What are the ingredients in SPIKEVAX?

SPIKEVAX 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 trihydrate
- sucrose

SPIKEVAX does not contain preservatives.

If you would like more information, talk to your healthcare provider or visit www.spikevax.com or call 1-866-MODERNA (1-866-663-3762).

Manufactured for:
Moderna US, Inc.
Princeton, NJ 08540

Patent(s): www.modernatx.com/patents
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