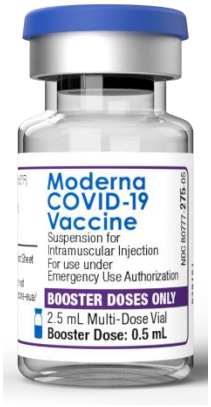
FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

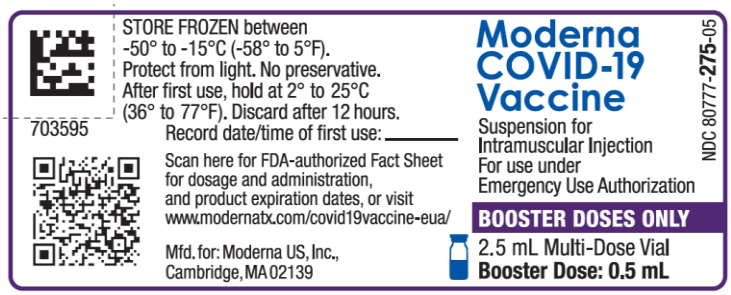
PRIMARY SERIES
6 years through 11 years of age

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 6 months of age and older.

There are 2 presentations of Moderna COVID-19 Vaccine authorized for use to provide primary series doses to individuals 6 years through 11 years of age:

- **The presentation supplied in a multiple-dose vial with a dark blue cap and a label with a purple border (see image below). The cartons and vial labels state "BOOSTER DOSES ONLY." This presentation may be used to provide primary series doses to individuals 6 years through 11 years of age. The Moderna COVID-19 Vaccine is not authorized to provide booster doses to individuals 6 years through 11 years of age.[1]**





[1] The multiple-dose vials with dark blue caps and labels with a purple border are authorized to provide 0.5 mL primary series doses to individuals 6 years through 11 years of age and to provide 0.5 mL booster doses to individuals 18 years of age and older.

- **The presentation supplied in a multiple-dose vial with a dark blue cap and a label with a teal border (currently not available). The cartons state "For age 6 years through 11 years." The vial labels state "Age 6y through 11y."**

This Fact Sheet pertains only to Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border which are authorized for use to provide a two-dose primary series to individuals 6 years through 11 years of age. The vaccine is also authorized to provide a third primary series dose to individuals 6 years through 11 years of age who have been determined to have certain kinds of immunocompromise.[2]

Moderna COVID-19 Vaccine supplied in multiple-dose vials with a dark blue cap and a label with a teal border intended for use in individuals 6 years through 11 years of age should not be used in individuals 6 months through 5 years of age, and individuals 12 years of age and older because of the potential for vaccine administration errors, including dosing errors.[3,4]

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

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

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[2] Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[3] Notwithstanding the age limitations for use of the different presentations of the Moderna COVID-19 Vaccine, individuals who will turn from 5 years to 6 years of age between doses in the primary series may receive, for any dose in the primary series, either: (1) the Moderna COVID-19 Vaccine authorized for use in individuals 6 months through 5 years of age (each 0.25 mL dose containing 25 mcg mRNA) supplied in multiple-dose vials with dark blue caps and labels with a magenta border; (2) the Moderna COVID-19 Vaccine authorized for use in individuals 6 years through 11 years of age (each 0.5 mL dose containing 50 mcg mRNA) supplied in multiple-dose vials with dark blue caps and labels with a purple border stating "BOOSTER DOSES ONLY"; or (3) the Moderna COVID-19 Vaccine authorized for use in individuals 6 years through 11 years of age (each 0.5 mL dose containing 50 mcg mRNA) supplied in multiple-dose vials with dark blue caps and labels with a teal border.

Similarly, individuals who will turn from 11 years to 12 years of age between doses in the primary series may receive, for any dose in the primary series, either: (1) the Moderna COVID-19 Vaccine authorized for use in individuals 6 years through 11 years of age (each 0.5 mL dose containing 50 mcg mRNA) supplied in multiple-dose vials with dark blue caps and labels with a purple border stating "BOOSTER DOSES ONLY"; (2) SPIKEVAX (COVID-19 Vaccine, mRNA) or the Moderna COVID-19 Vaccine authorized for use in individuals 12 years of age and older (each 0.5 mL dose containing 100 mcg mRNA) supplied in multiple-dose vials with red caps and labels with a light blue border; or (3) the Moderna COVID-19 Vaccine authorized for use in individuals 6 years through 11 years of age (each 0.5 mL dose containing 50 mcg mRNA) supplied in multiple-dose vials with dark blue caps and labels with a teal border.

[4] For primary vaccination of individuals 6 months through 5 years of age and 12 years of age and older, refer to the respective Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine.

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

The Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border is administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 6 years through 11 years of age.

A third primary series dose (0.5 mL) of the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border is authorized for administration at least 1 month following the second dose to individuals 6 years through 11 years of age with certain kinds of immunocompromise.

See this Fact Sheet for instructions for preparation and administration. This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.modernatx.com/covid19vaccine-eua.

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

DESCRIPTION OF COVID-19

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

DOSAGE AND ADMINISTRATION

Storage and Handling

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

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Frozen Storage

Store frozen between -50°C to -15°C (-58°F to 5°F).

Storage after Thawing

- Storage at 2°C to 8°C (36°F to 46°F):
    - Vials may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.
    - Vials should be discarded 12 hours after the first puncture.

- Storage at 8°C to 25°C (46°F to 77°F):
    - Vials may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours.
    - Vials should be discarded 12 hours after the first puncture.
    - Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.

Do not refreeze once thawed.

Thawed vials can be handled in room light conditions.

Transportation of Thawed Vials at 2°C to 8°C (36°F to 46°F)

If transport at -50°C to -15°C (-58°F to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2°C to 8°C (36°F to 46°F) when shipped using shipping containers which have been qualified to maintain 2°C to 8°C (36°F to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2°C to 8°C (36°F to 46°F), vials should not be refrozen and should be stored at 2°C to 8°C (36°F to 46°F) until use.

Dosing and Schedule

The Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border is administered as a primary series of two doses (0.5 mL each) 1 month apart to individuals 6 years through 11 years of age.

A third primary series dose (0.5 mL) of the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border is authorized for administration at least 1 month following the second dose to individuals 6 years through 11 years of age with certain kinds of immunocompromise.

Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vial with a dark blue cap and a label with a purple border and the Moderna COVID-19 Vaccine multiple-dose vial with a dark blue cap and a label with a teal border contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Verify that the vial of Moderna COVID-19 Vaccine has a dark blue cap and a label with a purple border or a dark blue cap and a label with a teal border.
- Thaw each vial before use following the instructions below.

Thawing Instructions for Moderna COVID-19 Vaccine Multiple-Dose Vials with Dark Blue Caps and Labels with a Purple Border or Multiple-Dose Vials with Dark Blue Caps and Labels with a Teal Border

Thaw in Refrigerator	Thaw at Room Temperature
Thaw between 2°C to 8°C (36°F to 46°F) for 2 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 15°C to 25°C (59°F to 77°F) for 45 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Do not administer if vaccine is discolored or contains other particulate matter.
- Each multiple-dose vial with a dark blue cap and a label with a purple border and each multiple-dose vial with a dark blue cap and a label with a teal border contains 5 doses of 0.5 mL.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- After the first 0.5 mL dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

Administration
Administer the Moderna COVID-19 Vaccine intramuscularly.

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

WARNINGS

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

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

Myocarditis and Pericarditis
Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

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

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

Limitations of Vaccine Effectiveness
The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

ADVERSE REACTIONS

Adverse Reactions in Clinical Trials
Adverse reactions in individuals 6 years through 11 years following administration of the primary series included pain at the injection site, fatigue, headache, myalgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, erythema at the injection site, swelling at the injection site, and arthralgia. *(See Full EUA Prescribing Information)*

Adverse Reactions in Post-Authorization Experience
Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine outside of clinical trials.

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

USE WITH OTHER VACCINES
There is no information on the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

INFORMATION TO PROVIDE TO VACCINE RECIPIENTS/CAREGIVERS
As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the "Fact Sheet for Recipients and Caregivers" (and provide a copy or direct the individual to the website www.modernatx.com/covid19vaccine-eua to obtain the Fact Sheet) prior to the individual receiving each dose of the Moderna COVID-19 Vaccine, including:

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

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

Provide a vaccination card to the recipient or their caregiver with the date when the recipient needs to return for the second dose of Moderna COVID-19 Vaccine.

Provide the **v-safe** information sheet to vaccine recipients/caregivers and encourage vaccine recipients to participate in **v-safe**. **V-safe** is a 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, visit: www.cdc.gov/vsafe.

MANDATORY REQUIREMENTS FOR MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION[5]

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

1. The Moderna COVID-19 Vaccine is authorized for use in individuals 6 months of age and older.

2. The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver information consistent with the "Fact Sheet for Recipients and Caregivers" prior to the individual receiving the Moderna COVID-19 Vaccine.

3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.

4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,

[5] Vaccination providers administering SPIKEVAX (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

- serious adverse events* (irrespective of attribution to vaccination),
- cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
- cases of COVID-19 that result in hospitalization or death.

Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words "Moderna COVID-19 Vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine to recipients.

*Serious adverse events are defined as:
- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

OTHER ADVERSE EVENT REPORTING TO VAERS AND MODERNATX, INC.
Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

ADDITIONAL INFORMATION
For general questions, visit the website or call the telephone number provided below.

To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please scan the QR code or visit the website provided below.

Website	Telephone number
www.modernatx.com/covid19vaccine-eua 	1-866-MODERNA (1-866-663-3762)

AVAILABLE ALTERNATIVES
There may be clinical trials or availability under EUA of other COVID-19 vaccines.

FEDERAL COVID-19 VACCINATION PROGRAM
This vaccine is being made available for emergency use exclusively through the CDC COVID-19 Vaccination Program (the Vaccination Program). Healthcare providers must enroll as providers in the Vaccination Program and comply with the provider requirements. Vaccination providers may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for administration. 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). For information regarding provider requirements and enrollment in the CDC COVID-19 Vaccination Program, see https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html.

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.

AUTHORITY FOR ISSUANCE OF THE EUA
The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency that justifies the emergency use of drugs and biological products during the COVID-19 Pandemic. In response, the FDA has issued an EUA for the unapproved product, Moderna COVID-19 Vaccine, for active immunization to prevent COVID-19.

FDA issued this EUA, based on ModernaTX, Inc.'s request and submitted data.

For the authorized uses, although limited scientific information is available, based on the totality of the scientific evidence available to date, it is reasonable to believe that the Moderna COVID-19 Vaccine may be effective for the prevention of COVID-19 in individuals as specified in the *Full EUA Prescribing Information*.

This EUA for the Moderna COVID-19 Vaccine will end when the Secretary of HHS determines that the circumstances justifying the EUA no longer exist or when there is a change in the approval status of the product such that an EUA is no longer needed.

For additional information about Emergency Use Authorization, visit FDA at:

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

COUNTERMEASURES INJURY COMPENSATION PROGRAM

The Countermeasures Injury Compensation Program (CICP) is a federal program that has been created to help pay for related costs of medical care and other specific expenses to compensate people injured after use of certain medical countermeasures. Medical countermeasures are specific vaccines, medications, devices, or other items used to prevent, diagnose, or treat the public during a public health emergency or a security threat. For more information about CICP regarding the vaccines to prevent COVID-19, visit http://www.hrsa.gov/cicp, email cicp@hrsa.gov, or call: 1-855-266-2427.

Moderna US, Inc.
Cambridge, MA 02139

Patent(s): www.modernatx.com/patents
Revised: June/17/2022

END SHORT VERSION FACT SHEET
Long Version (Full EUA Prescribing Information) Begins On Next Page

FULL EMERGENCY USE AUTHORIZATION (EUA)
PRESCRIBING INFORMATION

MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION

1 AUTHORIZED USE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older.

This EUA Prescribing Information pertains only to Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border, which are authorized for use in individuals 6 years through 11 years of age.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

The storage, preparation, and administration information in this EUA Prescribing Information apply to the Moderna COVID-19 Vaccine for individuals 6 years through 11 years of age, which is supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and in a multiple-dose vial with a dark blue cap and a label with a teal border.

2.1 Preparation for Administration

- The Moderna COVID-19 Vaccine multiple-dose vial with a dark blue cap and a label with a purple border and the Moderna COVID-19 Vaccine multiple dose-vial with a dark blue cap and a label with a teal border contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Verify that the vial of Moderna COVID-19 Vaccine has a dark blue cap and a label with a purple border or a dark blue cap and a label with a teal border.
- Thaw each vial before use following the instructions below.

Thawing Instructions for Moderna COVID-19 Vaccine Multiple-Dose Vials with Dark Blue Caps and Labels with a Purple Border or Multiple-Dose Vials with Dark Blue Caps and Labels with a Teal Border

Thaw in Refrigerator	Thaw at Room Temperature
Thaw between 2°C to 8°C (36°F to 46°F) for 2 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw between 15°C to 25°C (59°F to 77°F) for 45 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Do not administer if vaccine is discolored or contains other particulate matter.
- Each multiple-dose vial with a dark blue cap and a label with a purple border and each multiple-dose vial with a dark blue cap and a label with a teal border contains 5 doses of 0.5 mL.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.
- After the first 0.5 mL dose has been withdrawn, the vial should be held between 2°C to 25°C (36°F to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 12 hours. Do not refreeze.

2.2 Administration

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

The Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border is administered as a primary series of two

doses (0.5 mL each) 1 month apart to individuals 6 years through 11 years of age.

A third primary series dose (0.5 mL) of the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border is authorized for administration at least 1 month following the second dose to individuals 6 years through 11 years of age with certain kinds of immunocompromise.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for injection. Each dose of the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a purple border and in a multiple-dose vial with a dark blue cap and a label with a teal border for individuals 6 years through 11 years of age is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine *[see Description (13)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

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

Monitor Moderna COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).

5.2 Myocarditis and Pericarditis

Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. The observed risk is highest in males 18 through 24 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae. The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html).

5.3 Syncope

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

5.4 Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to the Moderna COVID-19 Vaccine.

5.5 Limitations of Vaccine Effectiveness

The Moderna COVID-19 Vaccine may not protect all vaccine recipients.

6 OVERALL SAFETY SUMMARY

It is MANDATORY for vaccination providers to report to the Vaccine Adverse Event Reporting System (VAERS) all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine.[6] To the extent feasible, provide a copy of the VAERS form to ModernaTX, Inc. Please see the REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS section for details on reporting to VAERS and ModernaTX, Inc.

In a clinical study, the adverse reactions in individuals 6 years through 11 years of age following administration of the primary series were pain at the injection site (98.4%), fatigue (73.1%), headache (62.1%), myalgia (35.3%), chills (34.6%), nausea/vomiting (29.3%), axillary swelling/tenderness (27.0%), fever (25.7%), erythema at the injection site (24.0%), swelling at the injection site (22.3%), and arthralgia (21.3%).

Post-Authorization Experience

Anaphylaxis and other severe allergic reactions, myocarditis, pericarditis, and syncope have been reported following administration of the Moderna COVID-19 Vaccine outside of clinical trials.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, approximately 39,000 participants aged 6 months and older received at least one dose of Moderna COVID-19 Vaccine in five clinical trials (NCT04283461, NCT04405076,

[6] Vaccination providers administering SPIKEVAX (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

NCT04470427, NCT04649151, and NCT04796896). In a sixth clinical trial (NCT04885907), 60 solid organ transplant recipients received a third dose of Moderna COVID-19 Vaccine.

Study 1 (NCT04470427) is a Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,346 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine[7] (n=15,184) or placebo (n=15,162). Study 3 (NCT04649151) is a Phase 2/3 randomized, placebo-controlled, observer-blind, clinical trial conducted in the United States involving 3,726 participants 12 years through 17 years of age who received at least one dose of Moderna COVID-19 Vaccine (n=2,486) or placebo (n=1,240). Study 4 (NCT04796896) includes an ongoing Phase 2/3 randomized, placebo-controlled, observer-blind clinical trial component conducted in the United States and Canada involving 10,390 participants 6 months through 11 years of age who received at least one dose of Moderna COVID-19 Vaccine (n=7,799) or placebo (n=2,591).

Individuals 6 Years Through 11 Years of Age

Safety data for Moderna COVID-19 Vaccine from the ongoing Phase 2/3 randomized, placebo-controlled, observer-blind, clinical trial conducted in the United States and Canada included data in 4,002 participants 6 years through 11 years of age who received at least one dose of Moderna COVID-19 Vaccine (n=3,007) or placebo (n=995) (Study 4). As of the data cutoff date of November 10, 2021, the median duration of blinded follow-up for safety was 51 days after Dose 2, and 1,284 participants had been followed for at least 2 months after Dose 2 (vaccine=1,006, placebo=218).

Demographic characteristics in Study 4 were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo. Overall, 50.8% were male, 49.2% were female, 18.5% were Hispanic or Latino, 65.6% were White, 10.0% were African American, 9.9% were Asian, 0.4% were American Indian or Alaska Native, <0.1% were Native Hawaiian or Pacific Islander, 2.1% were other races, and 10.6% were Multiracial.

Solicited Adverse Reactions

Local and systemic adverse reactions and use of antipyretic medication were solicited in an electronic diary for 7 days following each injection (i.e., day of vaccination and the next 6 days) among participants receiving Moderna COVID-19 Vaccine (n=3,006) and participants receiving placebo (n=994) with at least 1 documented dose. Events that persisted for more than 7 days were followed until resolution.

The reported number and percentage of the solicited local and systemic adverse reactions in participants 6 years through 11 years of age by dose in Study 4 are presented in Table 1.

[7] Moderna COVID-19 Vaccine is marketed as SPIKEVAX (COVID-19 Vaccine, mRNA), which is approved for use in individuals 18 years of age and older.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After Each Dose in Participants 6 Years Through 11 Years (Solicited Safety Set, Dose 1 and Dose 2)†

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,004) n (%)	**Dose 2** (N=2,988) n (%)	**Dose 1** (N=993) n (%)	**Dose 2** (N=969) n (%)
Local Adverse Reactions				
Pain	2,796 (93.1)	2,832 (94.8)	465 (46.8)	480 (49.5)
Pain, Grade 3[b]	28 (0.9)	81 (2.7)	0 (0)	2 (0.2)
Axillary swelling/tenderness	465 (15.5)	537 (18.0)	84 (8.5)	65 (6.7)
Axillary swelling/tenderness, Grade 3[b]	3 (<0.1)	3 (0.1)	1 (0.1)	2 (0.2)
Swelling (hardness) ≥25 mm	354 (11.8)	507 (17.0)	12 (1.2)	12 (1.2)
Swelling (hardness), Grade 3: >100 mm	19 (0.6)	20 (0.7)	1 (0.1)	0 (0)
Erythema (redness) ≥25 mm	349 (11.6)	559 (18.7)	13 (1.3)	10 (1.0)
Erythema (redness), Grade 3: >100 mm	16 (0.5)	33 (1.1)	1 (0.1)	1 (0.1)
Systemic Adverse Reactions				
Fatigue	1,298 (43.2)	1,925 (64.5)	334 (33.6)	335 (34.6)
Fatigue, Grade 3[c]	31 (1.0)	191 (6.4)	8 (0.8)	8 (0.8)
Headache	938 (31.2)	1,622 (54.3)	306 (30.8)	275 (28.4)
Headache, Grade 3[c]	18 (0.6)	119 (4.0)	4 (0.4)	8 (0.8)
Myalgia	438 (14.6)	843 (28.2)	96 (9.7)	105 (10.8)
Myalgia, Grade 3[c]	11 (0.4)	71 (2.4)	1 (0.1)	1 (0.1)
Arthralgia	260 (8.7)	482 (16.1)	75 (7.6)	84 (8.7)
Arthralgia, Grade 3[c]	3 (<0.1)	25 (0.8)	1 (0.1)	0 (0)
Chills	309 (10.3)	904 (30.3)	67 (6.7)	74 (7.6)
Chills, Grade 3[d]	3 (<0.1)	19 (0.6)	0 (0)	0 (0)
Nausea/vomiting	325 (10.8)	716 (24.0)	107 (10.8)	97 (10.0)
Nausea/vomiting, Grade 3[b]	5 (0.2)	19 (0.6)	0 (0)	0 (0)

	Moderna COVID-19 Vaccine		Placebo[a]	
	Dose 1 (N=3,004) n (%)	**Dose 2** (N=2,988) n (%)	**Dose 1** (N=993) n (%)	**Dose 2** (N=969) n (%)
Fever ≥38.0°C / >100.4°F	99 (3.3)	714 (23.9)	15 (1.5)	19 (2.0)
Fever, Grade 3: 39.0° - 40.0°C / 102.1° - 104.0°F	17 (0.6)	115 (3.8)	2 (0.2)	2 (0.2)
Use of antipyretic or pain medication	730 (24.3)	1,423 (47.6)	95 (9.6)	93 (9.6)

* 7 days included day of vaccination and the subsequent 6 days. Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary).
† No Grade 4 adverse reactions were reported.
[a] Placebo was a saline solution.
[b] Grade 3 pain, axillary swelling/tenderness, nausea/vomiting: Defined as prevents daily activity.
[c] Grade 3 fatigue, headache, myalgia, arthralgia: Defined as significant; prevents daily activity.
[d] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 2 to 3 days.

An assessment of reactogenicity among participants with evidence of prior SARS-CoV-2 infection (immunologic or virologic evidence of prior SARS-CoV-2 infection [defined as positive RT-PCR test and/or positive Elecsys immunoassay result at Day 1]) compared to those with no evidence of infection at baseline (negative RT-PCR test and negative Elecsys immunoassay result at Day 1) was conducted. In ages 6 years through 11 years, 8.6% of participants (vaccine=257, placebo=87) had evidence of prior SARS-CoV-2 infection at baseline. Table 2 presents the number and percentage of the solicited local and systemic adverse reactions in Moderna COVID-19 Vaccine participants starting within 7 days after each dose by SARS-CoV-2 status.

Table 2: Number and Percentage of Participants 6 Years Through 11 Years Who Received Vaccine With Solicited Local and Systemic Adverse Reactions Starting Within 7 Days* After Each Dose by SARS-CoV-2 Status (Solicited Safety Set, Dose 1 and Dose 2)†

	Baseline SARS-CoV-2 Positive		Baseline SARS-CoV-2 Negative	
	Dose 1 (N=257) n (%)	**Dose 2** (N= 255) n (%)	**Dose 1** (N=2,700) n (%)	**Dose 2** (N=2,686) n (%)
Local Adverse Reactions				
Pain	234 (91.1)	240 (94.1)	2,522 (93.4)	2,547 (94.8)
Pain, Grade 3[a]	3 (1.2)	8 (3.1)	23 (0.9)	72 (2.7)
Axillary swelling/tenderness	63 (24.5)	48 (18.8)	394 (14.6)	474 (17.6)

	Baseline SARS-CoV-2 Positive		Baseline SARS-CoV-2 Negative	
	Dose 1 (N=257) n (%)	**Dose 2** (N= 255) n (%)	**Dose 1** (N=2,700) n (%)	**Dose 2** (N=2,686) n (%)
Axillary swelling/tenderness, Grade 3[a]	1 (0.4)	0 (0)	2 (<0.1)	3 (0.1)
Swelling (hardness) ≥25 mm	29 (11.3)	29 (11.4)	317 (11.7)	468 (17.4)
Swelling (hardness), Grade 3: >100 mm	1 (0.4)	2 (0.8)	17 (0.6)	18 (0.7)
Erythema (redness) ≥25 mm	26 (10.1)	34 (13.3)	317 (11.7)	518 (19.3)
Erythema (redness), Grade 3: >100 mm	0 (0)	1 (0.4)	15 (0.6)	32 (1.2)
Systemic Adverse Reactions				
Fatigue	129 (50.2)	145 (56.9)	1,145 (42.4)	1,744 (65.0)
Fatigue, Grade 3[b]	11 (4.3)	14 (5.5)	20 (0.7)	169 (6.3)
Headache	127 (49.4)	134 (52.5)	796 (29.5)	1,458 (54.3)
Headache, Grade 3[b]	8 (3.1)	11 (4.3)	10 (0.4)	103 (3.8)
Myalgia	63 (24.5)	75 (29.4)	367 (13.6)	747 (27.8)
Myalgia, Grade 3[b]	2 (0.8)	3 (1.2)	9 (0.3)	63 (2.3)
Arthralgia	33 (12.8)	43 (16.9)	224 (8.3)	427 (15.9)
Arthralgia, Grade 3[b]	0 (0)	1 (0.4)	3 (0.1)	22 (0.8)
Chills	51 (19.8)	68 (26.7)	251 (9.3)	815 (30.4)
Chills, Grade 3[c]	1 (0.4)	1 (0.4)	2 (<0.1)	17 (0.6)
Nausea/vomiting	36 (14.0)	54 (21.2)	281 (10.4)	646 (24.1)
Nausea/vomiting, Grade 3[a]	1 (0.4)	0 (0)	4 (0.1)	18 (0.7)
Fever ≥38.0°C / >100.4°F	42 (16.3)	61 (23.9)	55 (2.0)	635 (23.6)
Fever, Grade 3: 39.0° - 40.0°C / 102.1° - 104.0°F	5 (1.9)	6 (2.4)	12 (0.4)	108 (4.0)

* 7 days included day of vaccination and the subsequent 6 days. Events were collected in the electronic diary (e-diary).

† No Grade 4 adverse reactions were reported.

[a] Grade 3 pain, axillary swelling/tenderness, nausea/vomiting: Defined as prevents daily activity.

[b] Grade 3 fatigue, headache, myalgia, arthralgia: Defined as significant; prevents daily activity.

[c] Grade 3 chills: Defined as prevents daily activity and requires medical intervention.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose. Serious adverse events and medically attended adverse events will be recorded for the entire study duration. As of November 10, 2021, among participants who had received at least 1 dose of vaccine or placebo (vaccine=3,007, placebo=995), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 29.6% of participants (n=891) who received Moderna COVID-19 Vaccine and 25.1% of participants (n=250) who received placebo. In these analyses, 98.6% of study participants had at least 28 days of follow-up after Dose 2.

During the 28-day follow-up period following any dose, lymphadenopathy-related events were reported by 1.8% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymph node pain, injection-site lymphadenopathy, and vaccination-site lymphadenopathy which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

During the 28-day follow-up period following any dose, hypersensitivity adverse events were reported in 4.3% of vaccine recipients and 2.1% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 2.7% of vaccine recipients and in 0.2% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

During the 28-day follow-up period following any dose, events of abdominal pain (including abdominal pain, abdominal pain upper, and abdominal pain lower) were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. Currently available information is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of November 10, 2021, serious adverse events were reported by 0.2% (n=6) of participants who received Moderna COVID-19 Vaccine and 0.2% (n=2) participants who received placebo. None of the events in the Moderna COVID-19 Vaccine group were considered related to vaccine. In these analyses, 98.6% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 51 days after Dose 2.

There were no notable patterns or imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Additional Safety Analyses

Participants 6 years through 11 years in Study 4 started to enter an open-label, observational phase after November 1, 2021. A long-term safety analysis was conducted in participants 6 years through 11 years from Study 4 who received Moderna COVID-19 Vaccine (n=3,007) with a cut-off date of February 21, 2022. In these analyses, the median duration of follow-up including both the blinded and open-label phases was 158 days after Dose 2. Through the cut-off date, there were no serious adverse events causally related to the vaccine.

Individuals 6 Months Through 5 Years of Age

Safety data for Moderna COVID-19 Vaccine from Study 4 included data in 6,388 participants 6 months through 5 years of age who received at least one dose of Moderna COVID-19 Vaccine (n=4,792) or placebo (n=1,596). As of the data cutoff date of February 21, 2022, the median duration of blinded follow-up for safety for participants 6 months through 23 months was 68 days after Dose 2. For participants 2 years to 5 years, the median duration of blinded follow-up for safety was 71 days after Dose 2.

For participants 6 months through 23 months, 51.1% were male, 48.9% were female, 13.2% were Hispanic or Latino, 79.0% were White, 3.1% were African American, 4.9% were Asian, 0.2% were American Indian or Alaska Native, 0.0% were Native Hawaiian or Pacific Islander, 1.5% were other races, and 10.6% were Multiracial. For participants 2 years through 5 years, 50.8% were male, 49.2% were female, 14.2% were Hispanic or Latino, 76.5% were White, 4.5% were African American, 6.0% were Asian, 0.4% were American Indian or Alaska Native, 0.3% were Native Hawaiian or Pacific Islander, 1.5% were other races, and 10.4% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose and follow-up is ongoing. Serious adverse events and medically attended adverse events will be recorded for the entire study duration.

As of February 21, 2022, among participants 6 months through 23 months of age who had received at least 1 dose of vaccine or placebo (vaccine=1,761, placebo=589), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 49.3% of participants (n=869) who received Moderna COVID-19 Vaccine and 48.2% of participants (n=284) who received placebo. In these analyses, 83.1% of study participants 6 months through 23 months of age had at least 28 days of follow-up after Dose 2. Among participants 2 years through 5 years of age who had received at least 1 dose of vaccine or placebo (vaccine=3,031, placebo=1,007), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 40.0% of participants (n=1,212) who received Moderna COVID-19 Vaccine and 37.5% of participants (n=378) who received placebo. In these analyses, 89.3% of study participants 2 years through 5 years of age had at least 28 days of follow-up after Dose 2.

During the 28-day follow-up period following any dose, lymphadenopathy-related events were reported by 1.5% of vaccine recipients and 0.2% of placebo recipients who were 6 months through 23 months of age and 0.9% of vaccine recipients and <0.1% of placebo recipients who were 2 years through 5 years of age. These events included lymphadenopathy, injection-site lymphadenopathy, and vaccination-site lymphadenopathy which were plausibly related to vaccination.

During the 28-day follow-up period following any dose, hypersensitivity adverse events were reported in 3.9% of vaccine recipients and 5.3% of placebo recipients who were 6 months through 23 months of age and 3.5% of vaccine recipients and 2.5% of placebo recipients who were 2 years through 5 years of age. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 1.2% of vaccine recipients and no placebo recipients who were 6 months through 23 months of age and 1.4% of vaccine recipients and <0.1% of placebo recipients who were 2 years through 5 years of age. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

During the 28-day follow-up period following any dose, events of abdominal pain (including abdominal pain, abdominal pain upper, and abdominal discomfort) were reported by 0.7% of vaccine recipients and 0.4% of placebo recipients who were 2 years through 5 years of age. Currently available information is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of February 21, 2022, serious adverse events were reported by 0.9% (n=15) of participants who received vaccine and 0.2% (n=1) of participants who received placebo who were 6 months through 23 months of age and 0.3% (n=9) of participants who received Moderna COVID-19 Vaccine and 0.2% (n=2) of participants who received placebo who were 2 years through 5 years of age. In these analyses, 83.1% of study participants 6 months through 23 months of age had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 68 days after Dose 2. In these analyses, 89.3% of study participants 2 years through 5 years of age had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 71 days after Dose 2.

In participants 6 months through 23 months of age who received the vaccine, a 1-year-old female experienced serious adverse events of a Grade 3 fever 6 hours after Dose 1 and a febrile convulsion 1 day after Dose 1. These events were considered related to vaccination. In participants 2 years through 5 years of age who received Moderna COVID-19 Vaccine, none of the events were considered related to vaccine.

Adolescents 12 Years Through 17 Years of Age

Safety data for Moderna COVID-19 Vaccine in adolescents were collected in an ongoing Phase 2/3 randomized, placebo-controlled, observer-blind, clinical trial conducted in the United States involving 3,726 participants 12 years through 17 years of age who received at least one dose of Moderna COVID-19 Vaccine (n=2,486) or placebo (n=1,240) (Study 3, NCT04649151). Overall, 51.4% were male, 48.6% were female, 11.6% were Hispanic or Latino, 83.9% were White, 3.4% were African American, 5.9% were Asian, 0.5% were American Indian or Alaska Native, <0.1% were Native Hawaiian or Pacific Islander, 1.0% were other races, and 4.5% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for up to 28 days following each dose. Serious adverse events and medically attended adverse events will be recorded for the entire study duration. As of May 8, 2021, among participants who had received at least 1 dose of vaccine or placebo (vaccine=2,486, placebo=1,240), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 20.5% of participants (n=510) who received Moderna COVID-19 Vaccine and 15.9% of participants (n=197) who received placebo. In these analyses, 97.3% of study participants had at least 28 days of follow-up after Dose 2.

During the 28-day follow-up period following any dose, lymphadenopathy-related events that were not necessarily captured in the 7-day e-diary were reported by 5.0% of vaccine recipients and 0.5% of placebo recipients. These events included lymphadenopathy, vaccination-site lymphadenopathy and injection-site lymphadenopathy which were plausibly related to vaccination.

During the 28-day follow-up period following any dose, hypersensitivity adverse events were reported in 1.8% of vaccine recipients and 0.6% of placebo recipients. Hypersensitivity events in the vaccine group included injection site rash and injection site urticaria, which are likely related to vaccination. Delayed injection site reactions that began >7 days after vaccination were reported in 0.9% of vaccine recipients and in no placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

As of May 8, 2021, serious adverse events were reported by 0.2% (n=6) of participants who received Moderna COVID-19 Vaccine and 0.2% (n=2) of participants who received placebo. In these analyses, 97.3% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 53 days after Dose 2.

There were no notable patterns or imbalances between treatment groups for specific categories of serious adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Additional Safety Analyses

Study 3 participants started to enter an open-label, observational phase after May 10, 2021. A long-term safety analysis was conducted in participants from Study 3 who received Moderna COVID-19 Vaccine (n=2,486) with a cut-off date of January 31, 2022. In these analyses, the median duration of follow-up including both the blinded and open-label phases was 312 days after Dose 2 and 95.6% of study participants have had at least 6 months of follow-up after Dose 2. Through the cut-off date, there were no serious adverse events causally related to the vaccine.

Adults 18 Years of Age and Older

The safety of Moderna COVID-19 Vaccine was evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States involving 30,346 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,184) or placebo (n=15,162) (Study 1, NCT04470427). Upon issuance of the Emergency Use Authorization (December 18, 2020) for Moderna COVID-19 Vaccine, participants were unblinded in a phased manner over a period of months to offer placebo participants Moderna COVID-19 Vaccine. The median duration of follow up for safety after the second injection during the blinded phase was 4 months. The median duration of follow up for safety after the second injection including both the blinded phase and the open-label phase was 6 months.

In Study 1, the median age of the population was 52 years (range 18-95); 22,826 (75.2%) participants were 18 to 64 years of age and 7,520 (24.8%) participants were 65 years of age and older. Overall, 52.6% of the participants were male, 47.4% were female, 20.5% were Hispanic or Latino, 79.2% were White, 10.2% were African American, 4.6% were Asian, 0.8% were American Indian or Alaska Native, 0.2% were Native Hawaiian or Pacific Islander, 2.0% were other races, and 2.1% were Multiracial. Demographic characteristics were similar between participants who received Moderna COVID-19 Vaccine and those who received placebo.

Unsolicited Adverse Events

Participants were monitored for unsolicited adverse events for 28 days following each dose. Serious adverse events and medically attended adverse events will be recorded for the entire study duration (2 years). Among the 30,346 participants who had received at least 1 dose of vaccine (N=15,184) or placebo (N=15,162), unsolicited adverse events that occurred within 28 days following any vaccination were reported by 31.3% of participants (n=4,752) who received Moderna COVID-19 Vaccine and 28.6% of participants (n=4,338) who received placebo.

During the 28-day follow-up period following any dose, lymphadenopathy-related events were reported by 1.7% of vaccine recipients and 0.8% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass.

During the 7-day follow-up period of any vaccination, hypersensitivity events of injection site rash or injection site urticaria, likely related to vaccination, were reported by 6 participants in the Moderna COVID-19 Vaccine group and none in the placebo group. Delayed injection site reactions that began >7 days after vaccination were reported in 1.4% of vaccine recipients and 0.7% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

In the blinded portion of the study, there were 8 reports of facial paralysis (including Bell's palsy) in the Moderna COVID-19 Vaccine group, and 3 in the placebo group. In the 28-day follow-up period there were two cases of facial paralysis in the Moderna COVID-19 Vaccine group, which occurred on 8 and 22 days, respectively, after vaccination, and one in the placebo group, which occurred 17 days after vaccination. Currently available information on facial paralysis is insufficient to determine a causal relationship with the vaccine.

In the blinded portion of the study, there were 50 reports of herpes zoster in the Moderna COVID-19 Vaccine group, and 23 in the placebo group. In the 28-day period after any vaccination, there were 22 cases of herpes zoster in the Moderna COVID-19 Vaccine group, and 15 in the placebo group. Currently available information on herpes zoster infection is insufficient to determine a causal relationship with the vaccine.

There were no other notable patterns or numerical imbalances between treatment groups for specific categories of adverse events (including other neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Serious Adverse Events

During the blinded phase of the study, serious adverse events were reported by 1.8% (n=268) of participants who received Moderna COVID-19 Vaccine and 1.9% (n=292) of participants who received placebo.

There were three serious adverse events of angioedema/facial swelling in the vaccine group in recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1-2 days after the second dose and was likely related to vaccination.

There were no other notable patterns or imbalances between treatment groups for specific categories of serious adverse events (including neurologic, neuro-inflammatory, and thrombotic events) that would suggest a causal relationship to Moderna COVID-19 Vaccine.

6.2 Post-Authorization Experience

The following adverse reactions have been identified during post-authorization use of the Moderna COVID-19 Vaccine. Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Cardiac Disorders: myocarditis, pericarditis
Immune System Disorders: anaphylaxis
Nervous System Disorders: syncope

8 REQUIREMENTS AND INSTRUCTIONS FOR REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS[8]

See Overall Safety Summary (Section 6) for additional information.

The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for the MANDATORY reporting of the listed events following Moderna COVID-19 Vaccine to the Vaccine Adverse Event Reporting System (VAERS)

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
- Cases of COVID-19 that results in hospitalization or death

*Serious Adverse Events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Instructions for Reporting to VAERS

The vaccination provider enrolled in the federal COVID-19 Vaccination Program should complete and submit a VAERS form to FDA using one of the following methods:

- Complete and submit the report online: https://vaers.hhs.gov/reportevent.html, or
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

IMPORTANT: When reporting adverse events or vaccine administration errors to VAERS, please complete the entire form with detailed information. It is important that the information reported to FDA be as detailed and complete as possible. Information to include:

- Patient demographics (e.g., patient name, date of birth)
- Pertinent medical history

[8] Vaccination providers administering SPIKEVAX (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.

- Pertinent details regarding admission and course of illness
- Concomitant medications
- Timing of adverse event(s) in relationship to administration of Moderna COVID-19 Vaccine
- Pertinent laboratory and virology information
- Outcome of the event and any additional follow-up information if it is available at the time of the VAERS report. Subsequent reporting of follow-up information should be completed if additional details become available.

The following steps are highlighted to provide the necessary information for safety tracking:

1. In Box 17, provide information on Moderna COVID-19 Vaccine and any other vaccines administered on the same day; and in Box 22, provide information on any other vaccines received within one month prior.
2. In Box 18, description of the event:
    a. Write "Moderna COVID-19 Vaccine EUA" as the first line
    b. Provide a detailed report of vaccine administration error and/or adverse event. It is important to provide detailed information regarding the patient and adverse event/medication error for ongoing safety evaluation of this unapproved vaccine. Please see information to include listed above.
3. Contact information:
    a. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
    b. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
    c. In Box 15, provide the address of the facility where vaccine was given (NOT the healthcare provider's office address).

Other Reporting Instructions

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

Email	Fax number	Telephone number
ModernaPV@modernatx.com	1-866-599-1342	1-866-MODERNA (1-866-663-3762)

10 DRUG INTERACTIONS

There are no data to assess the concomitant administration of the Moderna COVID-19 Vaccine with other vaccines.

11 USE IN SPECIFIC POPULATIONS

11.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

In a developmental toxicity study, 0.2 mL of a vaccine formulation containing the same quantity of nucleoside-modified messenger ribonucleic acid (mRNA) (100 mcg) and other ingredients included in a single primary series dose of Moderna COVID-19 Vaccine for individuals 12 years of age and older was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

11.2 Lactation

Risk Summary

Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

11.3 Pediatric Use

Moderna COVID-19 Vaccine is authorized for use in individuals 6 months through 17 years of age. This authorization is based on safety and effectiveness data in this age group and adults.

Moderna COVID-19 Vaccine is not authorized for use in individuals younger than 6 months of age.

11.4 Use in Immunocompromised Individuals

Safety and effectiveness of the Moderna COVID-19 Vaccine in individuals 6 months through 17 years of age with immunocompromise have been extrapolated from adult data. In an independent study (*Hall VG, Ferreira VH, Ku T et al. Randomized Trial of a Third Dose of mRNA-1273 Vaccine in Transplant Recipients. N Engl J Med 2021 DOI: 10.1056/NEJMc2111462;*

NCT04885907), safety and effectiveness of a third primary series dose of the Moderna COVID-19 Vaccine have been evaluated in participants who received solid organ transplants. In this study, in 60 adult participants who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years) who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no Grade 3 or Grade 4 events were reported. The administration of a third primary series vaccine dose appears to be only moderately effective in increasing antibody titers. Patients should be counseled to maintain physical precautions to help prevent COVID-19. In addition, close contacts of immunocompromised persons should be vaccinated, as appropriate for their health status.

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection.

Each 0.5 mL primary series dose of Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border contains 50 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus. Each 0.5 mL dose of the Moderna COVID-19 Vaccine supplied in a multiple-dose vial with a dark blue cap and a label with a teal border contains the following ingredients: a total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain a preservative.

The vial stoppers are not made with natural rubber latex.

14 CLINICAL PHARMACOLOGY

14.1 Mechanism of Action

The nucleoside-modified mRNA in the Moderna COVID-19 Vaccine is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

18 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA

18.1 Efficacy of Two-Dose Primary Series in Participants 18 Years and Older

Study 1 is an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial to evaluate the efficacy, safety, and immunogenicity of the Moderna COVID-19 Vaccine in participants 18 years of age and older in the United States (NCT04470427). Randomization was

stratified by age and health risk: 18 to <65 years of age without comorbidities (not at risk for progression to severe COVID-19), 18 to <65 years of age with comorbidities (at risk for progression to severe COVID-19), and 65 years of age and older with or without comorbidities. Participants who were immunocompromised and those with a known history of SARS-CoV-2 infection were excluded from the study. Participants with no known history of SARS-CoV-2 infection but with positive laboratory results indicative of infection at study entry were included. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 3 months before enrollment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 30,420 participants were randomized equally to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for efficacy and safety until 24 months after the second dose.

The primary efficacy analysis population (referred to as the Per-Protocol Set) included 28,207 participants who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine (n=14,134) or placebo (n=14,073), and had a negative baseline SARS-CoV-2 status. In the Per-Protocol Set, 47.4% were female, 19.7% were Hispanic or Latino; 79.5% were White, 9.7% were African American, 4.6% were Asian, and 2.1% other races. The median age of participants was 53 years (range 18-95) and 25.3% of participants were 65 years of age and older. Of the study participants in the Per-Protocol Set, 18.5% were at increased risk of severe COVID-19 due to at least one pre-existing medical condition (chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease, or HIV infection) regardless of age. Between participants who received Moderna COVID-19 Vaccine and those who received placebo, there were no notable differences in demographics or pre-existing medical conditions.

Efficacy Against COVID-19

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever (≥38ºC / ≥100.4°F), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s); or the participant must have experienced at least one of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, or clinical or radiographical evidence of pneumonia; and the participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. COVID-19 cases were adjudicated by a Clinical Adjudication Committee.

The median length of follow-up for efficacy for participants in the study was 9 weeks post Dose 2. There were 11 COVID-19 cases in the Moderna COVID-19 Vaccine group and 185 cases in the placebo group, with a vaccine efficacy of 94.1% (95% confidence interval of 89.3% to 96.8%).

Table 3: Primary Efficacy Analysis: COVID-19* in Participants 18 Years of Age and Older Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
14,134	11	3.328	14,073	185	56.510	94.1 (89.3, 96.8)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

The subgroup analyses of vaccine efficacy are presented in Table 4.

Table 4: Subgroup Analyses of Vaccine Efficacy: COVID-19* Cases Starting 14 Days After Dose 2 per Adjudication Committee Assessments – Per-Protocol Set

Age Subgroup (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI)†
	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
18 to <65	10,551	7	2.875	10,521	156	64.625	95.6 (90.6, 97.9)
≥65	3,583	4	4.595	3,552	29	33.728	86.4 (61.4, 95.2)

* COVID-19: symptomatic COVID-19 requiring positive RT-PCR result and at least two systemic symptoms or one respiratory symptom. Cases starting 14 days after Dose 2.
† VE and 95% CI from the stratified Cox proportional hazard model.

Severe COVID-19 was defined based on confirmed COVID-19 as per the primary efficacy endpoint case definition, plus any of the following: Clinical signs indicative of severe systemic illness, respiratory rate ≥30 per minute, heart rate ≥125 beats per minute, SpO2 ≤93% on room air at sea level or PaO2/FIO2 <300 mm Hg; or respiratory failure or ARDS (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure <90 mmHg, diastolic BP <60 mmHg or requiring vasopressors); or significant acute renal, hepatic, or neurologic dysfunction; or admission to an intensive care unit or death.

Among all participants in the Per-Protocol Set analysis, which included COVID-19 cases confirmed by an adjudication committee, no cases of severe COVID-19 were reported in the

Moderna COVID-19 Vaccine group compared with 30 cases reported in the placebo group (incidence rate 9.138 per 1,000 person-years). One PCR-positive case of severe COVID-19 in a vaccine recipient was awaiting adjudication at the time of the analysis.

18.2 Effectiveness of Two-Dose Primary Series in Individuals 6 Years Through 11 Years of Age

Study 4 includes an ongoing Phase 2/3 randomized, placebo-controlled, observer-blind, clinical trial component to evaluate the safety, reactogenicity, and effectiveness of the Moderna COVID-19 Vaccine in individuals ages 6 years through 11 years in the United States and Canada (NCT04796896). Participants with a known history of SARS-CoV-2 infection within 2 weeks of study vaccination were excluded from the study. A total of 4,016 participants were randomized 3:1 to receive 2 doses of the Moderna COVID-19 Vaccine or saline placebo 1 month apart. Participants will be followed for occurrence of COVID-19 and safety until 1 year after the last dose.

Effectiveness in individuals 6 years through 11 years of age is based on a comparison of immune responses in this age group to adults 18 through 25 years of age.

In Study 4, an analysis was conducted of SARS-CoV-2 50% neutralizing titers and seroresponse rates 28 days after Dose 2 in a subset of individuals 6 years through 11 years of age in Study 4 and participants 18 years through 25 years of age in Study 1 who had no immunologic or virologic evidence of prior SARS-CoV-2 at baseline. Noninferior immune responses as assessed by geometric mean 50% neutralizing titers and seroresponse rates were demonstrated in a comparison of individuals 6 years through 11 years of age to participants 18 years through 25 years of age (Table 5).

Table 5: Summary of Geometric Mean Titer Ratio and Seroresponse Rate – Comparison of Individuals 6 Years Through 11 Years of Age to Participants 18 Years Through 25 Years of Age – Per-Protocol Immunogenicity Set

		Moderna COVID-19 Vaccine			
		6 Years Through 11 Years n=320	**18 Years Through 25 Years n=295**	**6 Years Through 11 Years/ 18 Years Through 25 Years**	
Assay	**Time Point**	**GMT (95% CI)***	**GMT (95% CI)***	**GMT ratio (95% CI)[a]**	**Met Noninferiority Objective (Y/N)[b]**
SARS-CoV-2 neutralization assay – ID50 (titer)[c]	28 days after Dose 2	1610.2 (1456.6, 1780.0)	1299.9 (1171.2, 1442.7)	1.2 (1.1, 1.4)	Y
		Seroresponse % (95% CI)[d]	**Seroresponse % (95% CI)[d]**	**Difference in Seroresponse Rate % (95% CI)[e]**	
		99.1 (97.3, 99.8)	99.0 (97.1, 99.8)	0.1 (-1.9, 2.1)	

GMT = Geometric mean titer

* Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values greater than the upper limit of quantification (ULOQ) are replaced by the ULOQ if actual values are not available.

[a] The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the group variable (individuals in Study 4 and young adults in Study 1) as fixed effect. The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.

[b] Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMT ratio is greater than 0.67, with a point estimate of >0.8 and the lower bound of the 2-sided 95% CI for difference in seroresponse rate is greater than -10%, with a point estimate of >-5%.

[c] SARS-CoV-2 50% inhibitory dose (ID50) neutralization titers were determined using a SARS-CoV-2 Spike-Pseudotyped Virus Neutralization Assay. Quantification of SARS-CoV-2 neutralizing antibodies utilizes lentivirus particles expressing SARS-CoV-2 Spike protein on their surface and contains a firefly luciferase (Luc) reporter gene for quantitative measurements of infection by relative luminescence units (RLU). Neutralization is measured as the serum dilution at which RLU is reduced by 50% (ID50) relative to mean RLU in virus control wells virus but after subtraction of mean RLU in cell control wells.

[d] Seroresponse due to vaccination specific to pseudovirus neutralizing antibody ID50 titer at a subject level is defined in protocol as a change from below LLOQ to equal or above 4 x LLOQ, or at least a 4-fold rise if baseline is equal to or above LLOQ. Seroresponse 95% CI is calculated using the Clopper-Pearson method.

[e] Difference in seroresponse rate 95% CI is calculated using the Miettinen-Nurminen method.

In a descriptive analysis, vaccine efficacy could not be determined reliably. An insufficient number of COVID-19 cases were accrued in the Per-Protocol population starting 14 days after Dose 2 due to treatment unblinding and cross-over vaccination after the availability of an authorized COVID-19 vaccine in this age group.

18.3 Immunogenicity in Solid Organ Transplant Recipients

Immunogenicity of the Moderna COVID-19 Vaccine in children with immunocompromise has been extrapolated from adult data. An independent randomized-controlled study has been conducted in 120 adult participants who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years previously (range 1.99-6.75 years). A third primary series dose of the Moderna COVID-19 Vaccine was administered to 60 participants approximately 2 months after they had received a second dose; saline placebo was given to 60 individuals for comparison. Significant increases in levels of SARS-CoV-2 antibodies occurred four weeks after the third dose in 55.0% of participants in the Moderna COVID-19 Vaccine group (33 of 60) and 17.5% of participants in the placebo group (10 of 57).

19 HOW SUPPLIED/STORAGE AND HANDLING

The information in this section applies to the Moderna COVID-19 Vaccine that is supplied in multiple-dose vials with dark blue caps and labels with a teal border containing a volume of 2.5 mL. These multiple-dose vials are supplied as follows:

NDC 80777-277-99 Carton of 10 multiple-dose vials, each containing 5 doses of 0.5 mL

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Frozen Storage
Store frozen between -50°C to -15°C (-58°F to 5°F).

Storage after Thawing

- Storage at 2°C to 8°C (36°F to 46°F):
  - Vials may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 30 days prior to first use.
  - Vials should be discarded 12 hours after the first puncture.
- Storage at 8°C to 25°C (46°F to 77°F):
  - Vials may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours.
  - Vials should be discarded 12 hours after the first puncture.
  - Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.

Do not refreeze once thawed.

Thawed vials can be handled in room light conditions.

Transportation of Thawed Vials at 2°C to 8°C (36°F to 46°F)

If transport at -50°C to -15°C (-58°F to 5°F) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2°C to 8°C (36°F to 46°F) when shipped using shipping containers which have been qualified to maintain 2°C to 8°C (36°F to 46°F) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2°C to 8°C (36°F to 46°F), vials should not be refrozen and should be stored at 2°C to 8°C (36°F to 46°F) until use.

20 PATIENT COUNSELING INFORMATION

Advise the recipient or caregiver to read the Fact Sheet for Recipients and Caregivers.

The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. Advise recipient or caregiver that more information about IISs can be found at: https://www.cdc.gov/vaccines/programs/iis/about.html.

21 CONTACT INFORMATION

For general questions, send an email or call the telephone number provided below.

Email	Telephone number
medinfo@modernatx.com	1-866-MODERNA (1-866-663-3762)

This EUA Prescribing Information may have been updated. For the most recent Full EUA Prescribing Information, please visit www.modernatx.com/covid19vaccine-eua.

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Patent(s): www.modernatx.com/patents
Revised: June/17/2022