MODERNA COVID-19 VACCINE- cx-024414 injection, suspension
Moderna US, Inc.

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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)

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 18 years of age and older.

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 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.

The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered
as a series of two doses (0.5 mL each) 1 month apart.

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

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.

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light.

Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50ºC (-58ºF).

Vials may be stored refrigerated between 2º to 8ºC (36º to 46ºF) for up to 30 days prior to first use.

Vials may be stored between 8º to 25ºC (46º to 77ºF) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2º to 25ºC (36º to 77ºF). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

Transportation of Thawed Vials at 2º to 8ºC (36º to 46ºF)

If transport at -50º to -15ºC (-58º to 5ºF) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2º to 8ºC (35º to 46ºF) when shipped using shipping containers which have been qualified to maintain 2º to 8ºC (35º to 46ºF) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2º to 8ºC (35º to 46ºF), vials should not be refrozen and should be stored at 2º to 8ºC (35º to 46ºF) until use.

Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

Dose Preparation

- The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

<table>
<thead>
<tr>
<th>Vial</th>
<th>Thaw in Refrigerator</th>
<th>Thaw at Room Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum 11-Dose Vial (range: 10-11 doses)</td>
<td>Thaw in refrigerated conditions between 2º to 8ºC for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.</td>
<td>Alternatively, thaw at room temperature between 15º to 25ºC for 1 hour.</td>
</tr>
</tbody>
</table>
**Maximum 15-Dose Vial (range: 13-15 doses)**  
Thaw in refrigerated conditions between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering. Alternatively, thaw at room temperature between 15° to 25°C for 1 hour and 30 minutes.

- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. Do not shake. Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
  - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
  - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
  - Each dose must contain 0.5 mL of vaccine.
  - 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.
  - Pierce the stopper at a different site each time.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° 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**

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,
- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

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-
WARNINGS
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.


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

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

ADVERSE REACTIONS
Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site. (See Full EUA Prescribing Information)

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination 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
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 new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. V-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. V-safe also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information, visit: www.cdc.gov/vsafe.

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

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 18 years 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):
   1. vaccine administration errors whether or not associated with an adverse event,
   2. serious adverse events* (irrespective of attribution to vaccination),
   3. cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
   4. cases of COVID-19 that result in hospitalization or death.
5. 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.
6. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults, 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:
   1. Death;
   2. A life-threatening adverse event;
3. Inpatient hospitalization or prolongation of existing hospitalization;
4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
5. A congenital anomaly/birth defect;
6. 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.

<table>
<thead>
<tr>
<th>Email</th>
<th>Fax number</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:ModernaPV@modernatx.com">ModernaPV@modernatx.com</a></td>
<td>1-866-599-1342</td>
<td>1-866-MODERNA (1-866-663-3762)</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
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<td><a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a></td>
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AVAILABLE ALTERNATIVES

There is no approved alternative vaccine to prevent COVID-19. 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 in individuals 18 years of age and older.

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

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.


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

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Patent(s): www.modernatx.com/patents
Revised: Mar/31/2021
FULL EMERGENCY USE AUTHORIZATION (EUA) PRESCRIBING INFORMATION
MODERNA COVID-19 VACCINE

FULL EUA PRESCRIBING INFORMATION:
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4 CONTRAINDICATIONS
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21 CONTACT INFORMATION

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

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 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 Preparation for Administration
• The Moderna COVID-19 Vaccine multiple-dose vials contain a frozen suspension that...
does not contain a preservative and must be thawed prior to administration.

- Remove the required number of vial(s) from storage and thaw each vial before use following the instructions below.

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- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- The Moderna COVID-19 Vaccine is supplied in two multiple-dose vial presentations:
  - A multiple-dose vial containing a maximum of 11 doses: range 10-11 doses (0.5 mL each).
  - A multiple-dose vial containing a maximum of 15 doses: range 13-15 doses (0.5 mL each).
- Depending on the syringes and needles used for each dose, there may not be sufficient volume to extract more than 10 doses from the maximum of 11 doses vial or more than 13 doses from the maximum of 15 doses vial. Irrespective of the type of syringe and needle:
  - Each dose must contain 0.5 mL of vaccine.
  - 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.
  - Pierce the stopper at a different site each time.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° 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

Visually inspect each dose of the Moderna COVID-19 Vaccine in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent product-related particulates. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there are no other particulates and that no discoloration is observed.
- do not administer if vaccine is discolored or contains other particulate matter.

Administer the Moderna COVID-19 Vaccine intramuscularly.

2.3 Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a suspension for intramuscular injection. A single dose 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.


5.2 Altered Immunocompetence

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

5.3 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 Multi-inflammatory Syndrome (MIS) in adults, and hospitalized or fatal cases of COVID-19 following vaccination with the Moderna COVID-19 Vaccine. 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 clinical studies, the adverse reactions in participants 18 years of age and older were:
- Pain at the injection site (92.0%)
- Fatigue (70.0%)
- Headache (64.7%)
- Myalgia (61.5%)
- Arthralgia (46.4%)
- Chills (45.4%)
- Nausea/vomiting (23.0%)
- Axillary swelling/tenderness (19.8%)
- Fever (15.5%)
- Swelling at the injection site (14.7%)
- Erythema at the injection site (10.0%)

Severe allergic reactions, including anaphylaxis, have been reported following administration of the Moderna COVID-19 Vaccine during mass vaccination 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, 15,419 participants aged 18 years and older received at least one dose of Moderna COVID-19 Vaccine in three clinical trials (NCT04283461, NCT04405076, and NCT04470427).

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 30,351 participants 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,185) or placebo (n=15,166) (NCT04470427). At the time of vaccination, the mean age of the population was 52 years (range 18-95); 22,831 (75.2%) of participants were 18 to 64 years of age and 7,520 (24.8%) of participants were 65 years of age and older. Overall, 52.7% were male, 47.3% 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, 2.1% were other races, and 2.1% were Multiracial. Demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Solicited Adverse Reactions

Data on solicited local and systemic adverse reactions and use of antipyretic medication were collected 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=15,179) and participants receiving placebo (n=15,163) with at least 1
documented dose. Solicited adverse reactions were reported more frequently among vaccine participants than placebo participants.

The reported number and percentage of the solicited local and systemic adverse reactions by age group and dose are presented in Table 1 and Table 2, respectively.

Table 1: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 18-64 Years (Solicited Safety Set, Dose 1 and Dose 2)

<table>
<thead>
<tr>
<th>Local Adverse Reactions</th>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo a</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1 (N=11,406) n (%)</td>
<td>Dose 2 (N=10,985) n (%)</td>
</tr>
<tr>
<td>Pain</td>
<td>9,908 (86.9)</td>
<td>9,873 (89.9)</td>
</tr>
<tr>
<td>Pain, Grade 3 b</td>
<td>366 (3.2)</td>
<td>506 (4.6)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td>1,322 (11.6)</td>
<td>1,775 (16.2)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness, Grade 3 b</td>
<td>37 (0.3)</td>
<td>46 (0.4)</td>
</tr>
<tr>
<td>Swelling (hardness) ≥25 mm</td>
<td>767 (6.7)</td>
<td>1,389 (12.6)</td>
</tr>
<tr>
<td>Swelling (hardness), Grade 3 c</td>
<td>62 (0.5)</td>
<td>182 (1.7)</td>
</tr>
<tr>
<td>Erythema (redness) ≥25 mm</td>
<td>344 (3.0)</td>
<td>982 (8.9)</td>
</tr>
<tr>
<td>Erythema (redness), Grade 3 c</td>
<td>34 (0.3)</td>
<td>210 (1.9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Systemic Adverse Reactions</th>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo a</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dose 1 (N=11,406) n (%)</td>
<td>Dose 2 (N=10,985) n (%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4,384 (38.4)</td>
<td>7,430 (67.6)</td>
</tr>
<tr>
<td>Fatigue, Grade 3 d</td>
<td>120 (1.1)</td>
<td>1,174 (10.7)</td>
</tr>
<tr>
<td>Fatigue, Grade 4 e</td>
<td>1 (&lt;0.1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Headache</td>
<td>4,030 (35.3)</td>
<td>6,898 (62.8)</td>
</tr>
<tr>
<td>Headache, Grade 3 f</td>
<td>219 (1.9)</td>
<td>553 (5.0)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>2,699 (23.7)</td>
<td>6,769 (61.6)</td>
</tr>
<tr>
<td>Myalgia, Grade 3 d</td>
<td>73 (0.6)</td>
<td>1,113 (10.1)</td>
</tr>
</tbody>
</table>
Arthralgia | 1,893 (16.6) | 4,993 (45.5) | 1,327 (11.6) | 1,172 (10.7) \\
Arthralgia, Grade 3 | 47 (0.4) | 647 (5.9) | 29 (0.3) | 37 (0.3) \\
Arthralgia, Grade 4 | 1 (<0.1) | 0 (0) | 0 (0) | 0 (0) \\
Chills | 1,051 (9.2) | 5,341 (48.6) | 730 (6.4) | 658 (6.0) \\
Chills, Grade 3 | 17 (0.1) | 164 (1.5) | 8 (<0.1) | 15 (0.1) \\
Nausea/vomiting | 1,068 (9.4) | 2,348 (21.4) | 908 (8.0) | 801 (7.3) \\
Nausea/vomiting, Grade 3 | 6 (<0.1) | 10 (<0.1) | 8 (<0.1) | 8 (<0.1) \\
Fever | 105 (0.9) | 1,908 (17.4) | 37 (0.3) | 39 (0.4) \\
Fever, Grade 3 | 10 (<0.1) | 184 (1.7) | 1 (<0.1) | 2 (<0.1) \\
Fever, Grade 4 | 4 (<0.1) | 12 (0.1) | 4 (<0.1) | 2 (<0.1) \\
Use of antipyretic or pain medication | 2,656 (23.3) | 6,292 (57.3) | 1,523 (13.4) | 1,248 (11.4) \\

* 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).

a Placebo was a saline solution.
b Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.
c Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.
d Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.
e Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization.
f Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
g Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
h Grade 3 nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.
i Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.
j Grade 4 fever: Defined as >40.0°C / >104.0°F.

Table 2: Number and Percentage of Participants With Solicited Local and Systemic Adverse Reactions Within 7 Days* After Each Dose in Participants 65 Years and Older (Solicited Safety Set, Dose 1 and Dose 2)
<table>
<thead>
<tr>
<th>Reaction</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>2,782 (74.0)</td>
<td>3,070 (83.2)</td>
<td>481 (12.8)</td>
<td>437 (12.0)</td>
</tr>
<tr>
<td>Pain, Grade 3 b</td>
<td>50 (1.3)</td>
<td>98 (2.7)</td>
<td>32 (0.9)</td>
<td>18 (0.5)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness</td>
<td>231 (6.1)</td>
<td>315 (8.5)</td>
<td>155 (4.1)</td>
<td>97 (2.7)</td>
</tr>
<tr>
<td>Axillary swelling/tenderness, Grade 3 b</td>
<td>12 (0.3)</td>
<td>21 (0.6)</td>
<td>14 (0.4)</td>
<td>8 (0.2)</td>
</tr>
<tr>
<td>Swelling (hardness) ≥25 mm</td>
<td>165 (4.4)</td>
<td>400 (10.8)</td>
<td>18 (0.5)</td>
<td>13 (0.4)</td>
</tr>
<tr>
<td>Swelling (hardness), Grade 3 c</td>
<td>20 (0.5)</td>
<td>72 (2.0)</td>
<td>3 (&lt;0.1)</td>
<td>7 (0.2)</td>
</tr>
<tr>
<td>Erythema (redness) ≥25 mm</td>
<td>86 (2.3)</td>
<td>275 (7.5)</td>
<td>20 (0.5)</td>
<td>13 (0.4)</td>
</tr>
<tr>
<td>Erythema (redness), Grade 3 c</td>
<td>8 (0.2)</td>
<td>77 (2.1)</td>
<td>2 (&lt;0.1)</td>
<td>3 (&lt;0.1)</td>
</tr>
<tr>
<td><strong>Systemic Adverse Reactions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>1,251 (33.3)</td>
<td>2,152 (58.3)</td>
<td>851 (22.7)</td>
<td>716 (19.6)</td>
</tr>
<tr>
<td>Fatigue, Grade 3 d</td>
<td>30 (0.8)</td>
<td>254 (6.9)</td>
<td>22 (0.6)</td>
<td>20 (0.5)</td>
</tr>
<tr>
<td>Headache</td>
<td>921 (24.5)</td>
<td>1,704 (46.2)</td>
<td>723 (19.3)</td>
<td>650 (17.8)</td>
</tr>
<tr>
<td>Headache, Grade 3 e</td>
<td>52 (1.4)</td>
<td>106 (2.9)</td>
<td>34 (0.9)</td>
<td>33 (0.9)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>742 (19.7)</td>
<td>1,739 (47.1)</td>
<td>443 (11.8)</td>
<td>398 (10.9)</td>
</tr>
<tr>
<td>Myalgia, Grade 3 d</td>
<td>17 (0.5)</td>
<td>205 (5.6)</td>
<td>9 (0.2)</td>
<td>10 (0.3)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>618 (16.4)</td>
<td>1,291 (35.0)</td>
<td>456 (12.2)</td>
<td>397 (10.9)</td>
</tr>
<tr>
<td>Arthralgia, Grade 3 d</td>
<td>13 (0.3)</td>
<td>123 (3.3)</td>
<td>8 (0.2)</td>
<td>7 (0.2)</td>
</tr>
<tr>
<td>Chills</td>
<td>202 (5.4)</td>
<td>1,141 (30.9)</td>
<td>148 (4.0)</td>
<td>151 (4.1)</td>
</tr>
<tr>
<td>Chills, Grade 3 f</td>
<td>7 (0.2)</td>
<td>27 (0.7)</td>
<td>6 (0.2)</td>
<td>2 (&lt;0.1)</td>
</tr>
<tr>
<td>Nausea/vomiting</td>
<td>194 (5.2)</td>
<td>437 (11.8)</td>
<td>166 (4.4)</td>
<td>133 (3.6)</td>
</tr>
<tr>
<td>Nausea/vomiting, Grade 3 g</td>
<td>4 (0.1)</td>
<td>10 (0.3)</td>
<td>4 (0.1)</td>
<td>3 (&lt;0.1)</td>
</tr>
<tr>
<td>Nausea/vomiting, Grade 4 h</td>
<td>0 (0)</td>
<td>1 (&lt;0.1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Fever</td>
<td>10 (0.3)</td>
<td>370 (10.0)</td>
<td>7 (0.2)</td>
<td>4 (0.1)</td>
</tr>
</tbody>
</table>
Fever, Grade 3 i

<table>
<thead>
<tr>
<th></th>
<th>1 (0.1)</th>
<th>18 (0.5)</th>
<th>1 (&lt;0.1)</th>
<th>0 (0)</th>
</tr>
</thead>
</table>

Fever, Grade 4 j

<table>
<thead>
<tr>
<th></th>
<th>0 (0)</th>
<th>1 (&lt;0.1)</th>
<th>2 (&lt;0.1)</th>
<th>1 (&lt;0.1)</th>
</tr>
</thead>
</table>

Use of antipyretic or pain medication

|            | 673 (17.9) | 1,546 (41.9) | 477 (12.7) | 329 (9.0) |

* 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).

a Placebo was a saline solution.
b Grade 3 pain and axillary swelling/tenderness: Defined as any use of prescription pain reliever; prevents daily activity.
c Grade 3 swelling and erythema: Defined as >100 mm / >10 cm.
d Grade 3 fatigue, myalgia, arthralgia: Defined as significant; prevents daily activity.
e Grade 3 headache: Defined as significant; any use of prescription pain reliever or prevents daily activity.
f Grade 3 chills: Defined as prevents daily activity and requires medical intervention.
g Grade 3 Nausea/vomiting: Defined as prevents daily activity, requires outpatient intravenous hydration.
h Grade 4 Nausea/vomiting: Defined as requires emergency room visit or hospitalization for hypotensive shock.
i Grade 3 fever: Defined as ≥39.0° – ≤40.0°C / ≥102.1° – ≤104.0°F.
j Grade 4 fever: Defined as >40.0°C / >104.0°F.

Solicited local and systemic adverse reactions reported following administration of Moderna COVID-19 Vaccine had a median duration of 1 to 3 days.

Grade 3 solicited local adverse reactions were more frequently reported after Dose 2 than after Dose 1. Solicited systemic adverse reactions were more frequently reported by vaccine recipients after Dose 2 than after Dose 1.

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 of 2 years. As of November 25, 2020, among participants who had received at least 1 dose of vaccine or placebo (vaccine=15,185, placebo=15,166), unsolicited adverse events that occurred within 28 days following each vaccination were reported by 23.9% of participants (n=3,632) who received Moderna COVID-19 Vaccine and 21.6% of participants (n=3,277) who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2.

Lymphadenopathy-related events that were not necessarily captured in the 7-day e-diary were reported by 1.1% of vaccine recipients and 0.6% of placebo recipients. These events included lymphadenopathy, lymphadenitis, lymph node pain, vaccination-site lymphadenopathy, injection-site lymphadenopathy, and axillary mass, which were plausibly related to vaccination. This imbalance is consistent with the imbalance observed for solicited axillary swelling/tenderness in the injected arm.

Hypersensitivity adverse events were reported in 1.5% of vaccine recipients and 1.1% 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

18 (0.5)

1 (<0.1)

1 (0.1)
site reactions that began >7 days after vaccination were reported in 1.2% of vaccine recipients and 0.4% of placebo recipients. Delayed injection site reactions included pain, erythema, and swelling and are likely related to vaccination.

Throughout the same period, there were three reports of Bell’s palsy in the Moderna COVID-19 Vaccine group (one of which was a serious adverse event), which occurred 22, 28, and 32 days after vaccination, and one in the placebo group which occurred 17 days after vaccination. Currently available information on Bell’s palsy 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

As of November 25, 2020, serious adverse events were reported by 1.0% (n=147) of participants who received Moderna COVID-19 Vaccine and 1.0% (n=153) of participants who received placebo, one of which was the case of Bell’s palsy which occurred 32 days following receipt of vaccine.

In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

There were two serious adverse events of facial swelling in vaccine recipients with a history of injection of dermatological fillers. The onset of swelling was reported 1 and 2 days, respectively, after vaccination and was likely related to vaccination.

There was one serious adverse event of intractable nausea and vomiting in a participant with prior history of severe headache and nausea requiring hospitalization. This event occurred 1 day after vaccination 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.

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

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
- 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
- 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:
   1. Write “Moderna COVID-19 Vaccine EUA” as the first line
   2. 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:
   1. In Box 13, provide the name and contact information of the prescribing healthcare provider or institutional designee who is responsible for the report.
   2. In Box 14, provide the name and contact information of the best doctor/healthcare professional to contact about the adverse event.
   3. 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.

<table>
<thead>
<tr>
<th>Email</th>
<th>Fax number</th>
<th>Telephone number</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:ModernaPV@modernatx.com">ModernaPV@modernatx.com</a></td>
<td>1-866-599-1342</td>
<td>1-866-MODERNA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(1-866-663-3762)</td>
</tr>
</tbody>
</table>

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 human dose of Moderna COVID-19 Vaccine 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
Safety and effectiveness have not been assessed in persons less than 18 years of age. Emergency Use Authorization of Moderna COVID-19 Vaccine does not include use in individuals younger than 18 years of age.

11.4 Geriatric Use

Clinical studies of Moderna COVID-19 Vaccine included participants 65 years of age and older receiving vaccine or placebo, and their data contribute to the overall assessment of safety and efficacy. In an ongoing Phase 3 clinical study, 24.8% (n=7,520) of participants were 65 years of age and older and 4.6% (n=1,399) of participants were 75 years of age and older. Vaccine efficacy in participants 65 years of age and older was 86.4% (95% CI 61.4, 95.2) compared to 95.6% (95% CI 90.6, 97.9) in participants 18 to <65 years of age [see Clinical Trial Results and Supporting Data for EUA (18)]. Overall, there were no notable differences in the safety profiles observed in participants 65 years of age and older and younger participants [see Overall Safety Summary (6.1)].

13 DESCRIPTION

Moderna COVID-19 Vaccine is provided as a white to off-white suspension for intramuscular injection. Each 0.5 mL dose of Moderna COVID-19 Vaccine contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus.

Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.20 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

A 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 is ongoing 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), 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**

<table>
<thead>
<tr>
<th>Moderna COVID-19 Vaccine</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants (N)</td>
<td>Participants (N)</td>
</tr>
<tr>
<td>14,134</td>
<td>14,073</td>
</tr>
<tr>
<td>COVID-19 Cases (n)</td>
<td>COVID-19 Cases (n)</td>
</tr>
<tr>
<td>11</td>
<td>185</td>
</tr>
<tr>
<td>Incidence Rate of COVID-19 per 1,000 Person-Years</td>
<td>Incidence Rate of COVID-19 per 1,000 Person-Years</td>
</tr>
<tr>
<td>7.8</td>
<td>12.5</td>
</tr>
</tbody>
</table>

*COVID-19* refers to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) disease.
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

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

* 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.

19 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine Suspension for Intramuscular Injection Multiple-Dose Vials
are supplied as follows:

**NDC 80777-273-99**  Carton of 10 multiple-dose vials, each vial containing a maximum of
11 doses: range 10-11 doses (0.5 mL)

**NDC 80777-273-98**  Carton of 10 multiple-dose vials, each vial containing a maximum of
15 doses: range 13-15 doses (0.5 mL)

During storage, minimize exposure to room light.

Store frozen between -50º to -15ºC (-58º to 5ºF). Store in the original carton to protect from light.

Do not store on dry ice or below -50ºC (-58ºF). Use of dry ice may subject vials to temperatures colder than -50ºC (-58ºF).

Vials may be stored refrigerated between 2º to 8ºC (36º to 46ºF) for up to 30 days prior to first use. Do not refreeze.

Vials may be stored between 8º to 25ºC (46º to 77ºF) for a total of 24 hours.

After the first dose has been withdrawn, the vial should be held between 2º to 25ºC (36º to 77ºF). Vials should be discarded 12 hours after the first puncture.

Thawed vials can be handled in room light conditions.

Do not refreeze once thawed.

**Transportation of Thawed Vials at 2ºC to 8ºC (35ºF to 46ºF)**

If transport at -50º to -15ºC (-58º to 5ºF) is not feasible, available data support transportation of one or more thawed vials for up to 12 hours at 2º to 8ºC (35º to 46ºF) when shipped using shipping containers which have been qualified to maintain 2º to 8ºC (35º to 46ºF) and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2º to 8ºC (35º to 46ºF), vials should not be refrozen and should be stored at 2º to 8ºC (35º to 46ºF) 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.

<table>
<thead>
<tr>
<th>Email</th>
<th>Telephone number</th>
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<tbody>
<tr>
<td><a href="mailto:medinfo@modernatx.com">medinfo@modernatx.com</a></td>
<td>1-866-MODERNA</td>
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<tr>
<td></td>
<td>(1-866-663-3762)</td>
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FACT SHEET FOR RECIPIENTS AND CAREGIVERS

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

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

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

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

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

The Moderna COVID-19 Vaccine may not protect everyone.

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

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.
The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

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

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

Tell your vaccination provider about all of your medical conditions, including if you:
- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

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

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:
- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

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

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

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle. The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart. If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

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

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against
COVID-19 is currently unknown.

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

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

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

Side effects that have been reported in a clinical trial with the Moderna COVID-19 Vaccine include:

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

Side effects that have been reported during post-authorization use of the Moderna COVID-19 Vaccine include:

- Severe allergic reactions

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

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

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

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

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

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

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

WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

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

Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

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

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

**WHAT IF I AM PREGNANT OR BREASTFEEDING?**

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

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

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

**KEEP YOUR VACCINATION CARD**

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

**ADDITIONAL INFORMATION**

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

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

<table>
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<tr>
<th>Moderna COVID-19 Vaccine website</th>
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<tr>
<td><a href="http://www.modernatx.com/covid19vaccine-eua">www.modernatx.com/covid19vaccine-eua</a></td>
<td>1-866-MODERNA (1-866-663-3762)</td>
</tr>
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</table>

**HOW CAN I LEARN MORE?**

- Ask the vaccination provider
- Contact your state or local public health department

**WHERE WILL MY VACCINATION INFORMATION BE RECORDED?**

The vaccination provider may include your vaccination information in your state/local...
jurisdiction’s Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

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

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

**WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?**

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

**WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?**

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

**WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

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

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

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

Moderna US, Inc.
Cambridge, MA 02139
Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 04/2021

Package/Label Display Panel
NDC 80777-273-99
Moderna COVID-19 Vaccine
Suspension for Intramuscular Injection
For use under Emergency Use Authorization

Contents: 10 multiple-dose vials (each vial contains maximum of 11 doses of 0.5 mL).

Protect from light

STORE FROZEN/between -50° to -15°C (-58° to 5°F)

Package/Label Display Panel

NDC 80777-273-10
Moderna COVID-19 Vaccine
Suspension for Intramuscular Injection
For use under Emergency Use Authorization
Multiple-dose vial
(maximum 11 doses of 0.5 mL)

Package/Label Display Panel
NDC 80777-273-15
Moderna COVID-19 Vaccine
Suspension for Intramuscular Injection
For use under Emergency Use Authorization
Multiple-dose vial
(maximum 15 doses of 0.5 mL)

Package/Label Display Panel
NDC 80777-273-98
Moderna COVID-19 Vaccine
Suspension for Intramuscular Injection
For use under Emergency Use Authorization

Contents: 10 multiple-dose vials (each vial contains maximum of 15 doses of 0.5 mL).

Protect from light

STORE FROZEN/between -50° to -15°C (-58° to 5°F)

MODERNA COVID-19 VACCINE

cx-024414 injection, suspension

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**Labeler - Moderna US, Inc. (117626450)**

**Establishment**

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Revised: 4/2021

Moderna US, Inc.