

# **FACT SHEET FOR VACCINATION PROVIDERS EMERGENCY USE AUTHORIZATION (EUA) OF 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 vaccination errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death following administration of Moderna COVID-19 Vaccine. See “[MANDATORY REQUIREMENTS FOR THE MODERNA COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION](#)” for reporting requirements.

- The Moderna COVID-19 Vaccine is a suspension for intramuscular injection.
- The Moderna COVID-19 Vaccine is administered as two doses (0.5 mL each). The second dose is administered 1 month after the first dose.

See the [Full EUA Prescribing Information](#) for instructions for preparation and administration.

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](http://www.clinicaltrials.gov).

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see [www.modernatx.com/covid19vaccine-eua](http://www.modernatx.com/covid19vaccine-eua).

## **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**

#### Storage Prior to Use

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light. Do not store on dry ice or below

-40°C (-40°F).

Remove the required number of vial(s) from storage and thaw each vial before use. Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Unopened vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze.

#### Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

#### **Dosing and Schedule**

The Moderna COVID-19 Vaccine is administered intramuscularly as two doses (0.5 mL each). The second dose is administered 1 month after the first dose.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines. 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.

#### **Dose Preparation**

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that is **preservative-free** and must be thawed prior to administration.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. Let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not return the vial to the freezer.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Inspect Moderna COVID-19 Vaccine vials visually for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- A maximum of 10 doses can be withdrawn from the multiple-dose vial.
- 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 6 hours. Do not refreeze.

#### **Administration**

Visually inspect each dose of Moderna COVID-19 Vaccine in the dosing syringe prior to administration. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there is no discoloration.

If the visual inspection fails, do not administer the vaccine.

Administer the Moderna COVID-19 Vaccine intramuscularly in the deltoid muscle.

### **CONTRAINDICATION**

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

### **WARNINGS AND PRECAUTIONS**

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.

See the [Full EUA Prescribing Information](#) for additional Warnings and Precautions.

### **ADVERSE REACTIONS**

Common adverse reactions that have been reported for the Moderna COVID-19 Vaccine are pain at the injection site (91.6%), fatigue (68.5%), headache (63.0%), myalgia (59.6%), arthralgia (44.8%), chills (43.4%), gastrointestinal symptoms (22.2%), lymphadenopathy (19.2%), fever (14.8%), swelling at the injection site (14.4%), and erythema at the injection site (9.7%).

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 the Fact Sheet) prior to the individual receiving 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 significant known and potential risks and benefits of the Moderna COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- The recipient or their caregiver has the option to accept or refuse the Moderna COVID-19 Vaccine.

Provide a COVID-19 vaccination card to recipients as documentation of the first dose of Moderna COVID-19 Vaccine and to remind them when a second dose should be administered.

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](http://www.clinicaltrials.gov).

## **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 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. Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older.
2. The vaccination provider enrolled in the federal COVID-19 Vaccination Program must communicate to the individual receiving the Moderna COVID-19 Vaccine information consistent with the “Fact Sheet for Recipients and Caregivers” prior to the individual receiving the Moderna COVID-19 Vaccine.
3. The vaccination provider enrolled in the federal COVID-19 Vaccination Program 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,
  - serious adverse events\* (irrespective of attribution to vaccination),
  - cases of Multisystem Inflammatory Syndrome (MIS), 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> or by calling 1-800-822-7967. The reports should include the words “Moderna COVID-19 Vaccine EUA” in the description section of the report.

4. The vaccination provider enrolled in the federal COVID-19 Vaccination Program is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS 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 REPORTING REQUIREMENTS**

In addition, you must report 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), and cases of COVID-19 that result in hospitalization or death to Moderna by calling 1-866-MODERNA (1-866-663-3762) or by providing a copy of the VAERS form to:

Moderna

Fax: 1-866-599-1342

E-mail: ModernaPV@modernatx.com

## **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 the Moderna COVID-19 Vaccine to prevent COVID-19. 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.

As a vaccination provider, you must comply with the mandatory requirements of the EUA (see above).

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

Although limited scientific information is available, based on the scientific evidence available to date, it is reasonable to expect 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 Moderna COVID-19 Vaccine used to prevent COVID-19, visit <http://www.hrsa.gov/cicp>, email [cicp@hrsa.gov](mailto:cicp@hrsa.gov), or call: 1-855-266-2427.

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Patent(s): [www.modernatx.com/patents](http://www.modernatx.com/patents)  
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# MODERNA COVID-19 VACCINE

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### FULL EUA PRESCRIBING INFORMATION: CONTENTS\*

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## 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) in individuals 18 years of age and older.

## 2 DOSAGE AND ADMINISTRATION

### 2.1 Storage and Handling

#### Storage Prior to Use

The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light. Do not store on dry ice or below -40°C (-40°F).

Remove the required number of vial(s) from storage and thaw each vial before use. Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Unopened vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze.

#### Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.



## 2.2 Dosing and Schedule

The Moderna COVID-19 Vaccine is administered intramuscularly as two doses (0.5 mL each). The second dose is administered 1 month after the first dose.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines. 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.

## 2.3 Dose Preparation

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that is **preservative-free** and must be thawed prior to administration.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. Let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not return the vial to the freezer.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
- Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Inspect Moderna COVID-19 Vaccine vials visually for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
- A maximum of 10 doses can be withdrawn from the multiple-dose vial.
- 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 for first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.

## 2.4 Administration

Visually inspect each dose of Moderna COVID-19 Vaccine in the dosing syringe prior to administration. During the visual inspection,

- verify the final dosing volume of 0.5 mL.
- confirm there is no discoloration.

If the visual inspection fails, do not administer the vaccine.

Administer the Moderna COVID-19 Vaccine intramuscularly in the deltoid muscle.

## 3 DOSAGE FORMS AND STRENGTHS

Moderna COVID-19 Vaccine is a sterile suspension for intramuscular administration available in multiple-dose vials containing a maximum of 10 doses of 0.5 mL each.

## 4 CONTRAINDICATIONS

Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to a previous dose of the Moderna COVID-19



Vaccine or any component of the Moderna COVID-19 Vaccine [see Full EUA Prescribing Information, Product Description (11)].

## **5 WARNINGS AND PRECAUTIONS**

### **5.1 Managing 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 Syncope**

Syncope (fainting) can occur in association with administration of injectable vaccines, including Moderna COVID-19 Vaccine. Procedures should be in place to avoid falling and to restore cerebral perfusion following syncope.

### **5.3 Altered Immunocompetence**

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

### **5.4 Persons at Risk of Bleeding**

As with other intramuscular injections, Moderna COVID-19 Vaccine should be given with caution in individuals with bleeding disorders, such as hemophilia or on anticoagulant therapy, to avoid the risk of hematoma following the injection.

### **5.5 Acute Illness**

Consideration should be given to postponing immunization in persons with severe febrile illness or acute infection. Persons with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved.

### **5.6 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 complete a Vaccine Adverse Event Reporting System (VAERS) Form to report all vaccine administration errors, all serious adverse events, cases of Multi-inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death following Moderna COVID-19 Vaccine. Please see the ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS REPORTING REQUIREMENTS AND INSTRUCTIONS (Section 7) for details on VAERS reporting.**

### **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. There is the possibility that broad use of Moderna COVID-19 Vaccine could reveal adverse reactions not observed in clinical trials.

Overall, 15,419 subjects 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 30,350 subjects 18 years of age and older who received at least one dose of Moderna COVID-19 Vaccine (n=15,184) or placebo (n=15,165) administered according to a 0- and 1-month schedule (NCT04470427). At the time of vaccination, the mean age of the population was 51.4 years (range 18-95); 22,830 (75.2%) subjects were 18 to 64 years of age and 7,520 (24.8%) subjects were 65 years of age and older. Overall, 52.7% were male, 20.5% were Hispanic or Latino, and 10.2% were African American.

### Solicited Adverse Reactions

Data on solicited local and systemic adverse reactions were collected using standardized diary cards for 7 days following each injection of vaccine or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n=15,176 receiving Moderna COVID-19 Vaccine, n=15,162 receiving placebo with at least 1 documented dose). Solicited adverse reactions were reported more frequently among vaccine subjects than placebo subjects. The percentages of subjects reporting each solicited local adverse reaction and each solicited systemic adverse reaction following administration of Moderna COVID-19 Vaccine (both doses combined) were pain at the injection site (91.6%), lymphadenopathy (19.2%), swelling at the injection site (14.4%), erythema at the injection site (9.7%); and fatigue (68.5%), headache (63.0%), myalgia (59.6%), arthralgia (44.8%), chills (43.4%), gastrointestinal symptoms (22.2%), fever (14.8%), respectively.

The reported frequencies of the solicited local and systemic adverse reactions (overall per subject), by age group, are presented in [Table 1](#).

**Table 1. Percentage of Subjects with Solicited Local and Systemic Adverse Reactions within 7 Days\* of either Dose of Vaccine/Placebo by Age Group (Total Vaccinated Cohort with Diary Card)**

	Aged 18-64 Years		Aged ≥65 Years		Overall	
	Moderna COVID-19 Vaccine (N=11,410) n (%)	Placebo† (N=11,412) n (%)	Moderna COVID-19 Vaccine (N=3,766) n (%)	Placebo† (N=3,750) n (%)	Moderna COVID-19 Vaccine (N=15,176) n (%)	Placebo† (N=15,162) n (%)
<b>Local Adverse Reactions</b>						
Pain	10,590 (92.8)	3,224 (28.3)	3,311 (87.9)	751 (20.0)	13,901 (91.6)	3,975 (26.2)
Pain, Grade 3‡	760 (6.7)	42 (0.4)	141 (3.7)	48 (1.3)	901 (5.9)	90 (0.6)
Lymphadenopathy	2,447 (21.4)	858 (7.5)	467 (12.4)	216 (5.8)	2,914 (19.2)	1,074 (7.1)

Lymphadenopathy, Grade 3	78 (0.7)	23 (0.2)	30 (0.8)	21 (0.6)	108 (0.7)	44 (0.3)
Swelling (hardness)	1,715 (15.0)	65 (0.6)	468 (12.4)	30 (0.8)	2,183 (14.4)	95 (0.6)
Swelling (hardness), Grade 3	232 (2.0)	6 ( $<0.1$ )	86 (2.3)	10 (0.3)	318 (2.1)	16 (0.1)
Erythema (redness)	1,145 (10.0)	82 (0.7)	325 (8.6)	32 (0.9)	1,470 (9.7)	114 (0.8)
Erythema (redness), Grade 3 (>100 mm)	236 (2.1)	22 (0.2)	83 (2.2)	5 (0.1)	319 (2.1)	27 (0.2)
<b>Systemic Adverse Reactions</b>						
Fatigue	7,986 (70.0)	4,279 (37.5)	2,407 (63.9)	1,191 (31.8)	10,393 (68.5)	5,470 (36.1)
Fatigue, Grade 3 <sup>§</sup>	1,181 (10.4)	155 (1.4)	270 (7.2)	42 (1.1)	1,451 (9.6)	197 (1.3)
Fatigue, Grade 4 <sup>¶</sup>	1 ( $<0.1$ )	0 (0)	0 (0)	0 (0)	1 ( $<0.1$ )	0 (0)
Headache	7,585 (66.5)	4,453 (39.0)	1,981 (52.6)	1,074 (28.6)	9,566 (63.0)	5,527 (36.5)
Headache, Grade 3 <sup>§</sup>	686 (6.0)	273 (2.4)	147 (3.9)	64 (1.7)	833 (5.5)	337 (2.2)
Myalgia	7,125 (62.4)	2,378 (20.8)	1,914 (50.8)	674 (18.0)	9,039 (59.6)	3,052 (20.1)
Myalgia, Grade 3 <sup>§</sup>	1,087 (9.5)	76 (0.7)	215 (5.7)	19 (0.5)	1,302 (8.6)	95 (0.6)
Arthralgia	5,315 (46.6)	1,945 (17.0)	1,488 (39.5)	661 (17.6)	6,803 (44.8)	2,606 (17.2)
Arthralgia, Grade 3 <sup>§</sup>	640 (5.6)	64 (0.6)	131 (3.5)	15 (0.4)	771 (5.1)	79 (0.5)
Arthralgia, Grade 4 <sup>¶</sup>	1 ( $<0.1$ )	0 (0)	0 (0)	0 (0)	1 ( $<0.1$ )	0 (0)
Chills	5,388 (47.2)	1,177 (10.3)	1,192 (31.7)	262 (7.0)	6,580 (43.4)	1,439 (9.5)
Chills, Grade 3 <sup>§</sup>	167 (1.5)	22 (0.2)	32 (0.8)	8 (0.2)	199 (1.3)	30 (0.2)
Gastrointestinal symptoms <sup>#</sup>	2,813 (24.7)	1,410 (12.4)	553 (14.7)	269 (7.2)	3,366 (22.2)	1,679 (11.1)
Gastrointestinal symptoms, Grade 3 <sup>§#</sup>	14 (0.1)	16 (0.1)	13 (0.3)	7 (0.2)	27 (0.2)	23 (0.2)
Gastrointestinal symptoms, Grade 4 <sup>#¶</sup>	0 (0)	0 (0)	1 ( $<0.1$ )	0 (0)	1 ( $<0.1$ )	0 (0)
Fever <sup>**</sup>	1,880 (16.5)	76 (0.7)	372 (9.9)	12 (0.3)	2,252 (14.8)	88 (0.6)
Fever, Grade 3 <sup>††</sup>	178 (1.6)	2 ( $<0.1$ )	18 (0.5)	1 ( $<0.1$ )	196 (1.3)	3 ( $<0.1$ )
Fever, Grade 4 <sup>‡‡</sup>	14 (0.1)	6 ( $<0.1$ )	1 ( $<0.1$ )	3 ( $<0.1$ )	15 ( $<0.1$ )	9 ( $<0.1$ )

N=Total vaccinated cohort for safety included all subjects with at least 1 documented dose.

\* 7 days included day of vaccination and the subsequent 6 days.

EUA Fact Sheet for Healthcare Providers and Full EUA Prescribing Information  
MODERNA COVID-19 VACCINE

Draft November 26, 2020

† Placebo was a saline solution.

‡ Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.

§ Grade 3 fatigue, headache, myalgia, arthralgia, chills, gastrointestinal symptoms: Defined as preventing normal activity.

¶ Grade 4 fatigue, arthralgia: Defined as requires emergency room visit or hospitalization

# Gastrointestinal symptoms = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

|| Grade 4 gastrointestinal symptoms: Defined as requires emergency room visit or hospitalization for hypotensive shock.

\*\* Fever defined as  $\geq 37.5^{\circ}\text{C}/99.5^{\circ}\text{F}$  for oral, axillary, or tympanic route, or  $\geq 38^{\circ}\text{C}/100.4^{\circ}\text{F}$  for rectal route.

†† Grade 3 fever: Defined as  $>39.0^{\circ}\text{C}/102.2^{\circ}\text{F}$ .

‡‡ Grade 4 fever: Defined as  $>40^{\circ}\text{C}/104^{\circ}\text{F}$ .

The majority of solicited local and systemic adverse reactions seen with Moderna COVID-19 Vaccine had a median duration of 2 to 3 days.

There were no differences in the proportions of vaccine subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Solicited systemic adverse reactions were more frequently reported by vaccine subjects after Dose 2 than after Dose 1, including fatigue (65.2% and 37.2%, respectively), myalgia (57.6% and 22.7%, respectively), chills (43.7% and 8.3%, respectively) and arthralgia (42.6% and 16.6%, respectively). Grade 3 solicited systemic adverse reactions (fatigue, myalgia, arthralgia, and headache) were reported more frequently by subjects after Dose 2 (9.7%, 8.8%, 5.2%, and 4.5%, respectively) than after Dose 1 (1.1%, 0.5%, 0.4%, and 1.8%, respectively).

### Unsolicited Adverse Events

Unsolicited adverse events that occurred within 28 days following each vaccination were reported by 21.9% of subjects (n=3,325) who received Moderna COVID-19 Vaccine and 19.4% of subjects (n=2,949) who received placebo (total vaccination cohort). Unsolicited adverse events that occurred in  $\geq 1\%$  of subjects who received the Moderna COVID-19 Vaccine and at a rate at least 1.5-fold higher than placebo included injection site pain (1.0% vs 0.3%).

### Serious Adverse Events

Serious adverse events were reported at similar rates in subjects who received Moderna COVID-19 Vaccine (0.5%) and placebo (0.6%) from the first administered dose up to 28 days following the last injection. Serious adverse events were at similar rates in subjects who received Moderna COVID-19 Vaccine (0.7%) and placebo (0.8%) from the first administered dose until last observation.

### Deaths

From the first administered dose up until the last observation, four deaths ( $<0.1\%$ ) have been reported in subjects who received Moderna COVID-19 Vaccine and four deaths ( $<0.1\%$ ) in subjects who received placebo. The causes of death were similar to the types of events typically reported in an adult and elderly population.

## 7 ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS REPORTING REQUIREMENTS AND INSTRUCTIONS

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:

- 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)
- 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.

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](mailto: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:
  - 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).

## **8 OTHER REPORTING REQUIREMENTS**

In addition, you must report the events described in Adverse Events and Vaccine Administration Errors Reporting Requirements and Instructions ([Section 7](#)) to Moderna by calling 1-866-MODERNA (1-866-663-3762) or by providing a copy of the VAERS form to:

Moderna

Fax: 1-866-599-1342

E-mail: ModernaPV@modernatx.com

## **9 DRUG INTERACTIONS**

### **9.1 Co-Administration with Other Vaccines**

There is no information to assess the co-administration of the Moderna COVID-19 Vaccine with other vaccines.

## **10 USE IN SPECIFIC POPULATIONS**

### **10.1 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

No adequate and well-controlled studies of Moderna COVID-19 Vaccine use in pregnant women have been conducted. There are no completed developmental toxicity studies of Moderna COVID-19 Vaccine in animals. Therefore, use of Moderna COVID-19 Vaccine is not recommended in pregnant women.

## **10.2 Lactation**

### **Risk Summary**

It is not known whether Moderna COVID-19 Vaccine is excreted in human milk. Data are not available to assess the effects of Moderna COVID-19 Vaccine on the breastfed infant or on milk production/excretion. Therefore, use of Moderna COVID-19 Vaccine is not recommended in breastfeeding mothers.

## **10.3 Pediatric Use**

Safety and effectiveness have not been assessed in persons less than 18 years of age.

## **10.4 Geriatric Use**

In an ongoing Phase 3 clinical study, the safety and efficacy of Moderna COVID-19 Vaccine was assessed in individuals 18 years of age and older, including 3527 subjects 65 years of age and older. In an interim analysis, the efficacy of Moderna COVID-19 Vaccine was consistent between older subjects ( $\geq 65$  years) and younger subjects (18-64 years). *[see Full EUA Prescribing Information, Clinical Trial Results and Supporting Data for EUA (13)]* [Section 2.5.4.2.3] Subjects 65 years of age and older reported solicited local and systemic adverse reactions at a lower rate than subjects 18-64 years of age. *[see Full EUA Prescribing Information, Clinical Trials Experience (6.1)]*

## **11 PRODUCT DESCRIPTION**

Moderna COVID-19 Vaccine is a sterile lipid nanoparticle (LNP) suspension for intramuscular injection comprised of a synthetic messenger ribonucleic acid (mRNA) encoding the pre-fusion stabilized Spike glycoprotein of SARS-CoV-2 virus and four lipids. The synthetic mRNA is manufactured in a cell-free, in vitro transcription reaction and formulated with SM-102 (a proprietary ionizable lipid), PEG2000-DMG, cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) to form the mRNA/lipid nanoparticles.

Moderna COVID-19 Vaccine is provided as a sterile suspension for intramuscular injection and is white to off-white in appearance. Each 0.5 mL dose contains 100 mcg RNA and a total lipid content of 1.93 mg in tris buffer (0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride), 0.043 mg acetic acid, 0.12 mg sodium acetate, and 43.5 mg sucrose.

Moderna COVID-19 Vaccine does not contain any preservatives, antibiotics, adjuvants, or human- or animal-derived materials. The vial stopper does not contain natural rubber latex.

## **12 CLINICAL PHARMACOLOGY**

### **12.1 Mechanism of Action**



Moderna COVID-19 Vaccine encodes for the pre-fusion stabilized Spike protein of SARS-CoV-2. After intramuscular injection, cells take up the lipid nanoparticle, effectively delivering the mRNA sequence into cells for translation into protein. The mRNA delivery system is based on the principle and observation that cells in vivo can take up mRNA, translate it, and express protein antigen(s) in the desired conformation. The delivered mRNA does not enter the cellular nucleus or interact with the genome, is nonreplicating, and is expressed transiently. The protein undergoes post-translational modification and trafficking resulting in properly folded, fully functional Spike protein that is inserted into the cellular membrane of the expressing cell(s). The Spike protein is membrane bound, mimicking the presentation of natural infection.

The expressed Spike protein of SARS-CoV-2 is then recognized by immune cells as a foreign antigen which elicits both T-cell and B-cell responses. The immune response to the Spike protein results in functional Ab and T-cell responses and in the generation of memory immune cell populations.

The specific mechanism of protection for the SARS-CoV-2 virus remains under investigation.

### **13 CLINICAL TRIAL RESULTS AND SUPPORTING DATA FOR EUA**

Moderna COVID-19 Vaccine is being evaluated in an ongoing Phase 3 randomized, placebo-controlled, observer-blind clinical trial conducted in the United States in subjects aged 18 years and older who were at increased risk of COVID-19 disease (NCT04470427). In addition, pre-specified cohorts of subjects who were either  $\geq 65$  years of age or 18 to  $< 65$  years of age with comorbid medical conditions were included. A total of 30,350 subjects were followed for a median of 78 days (range: 0-108) for the development of COVID-19 disease.

The primary efficacy analysis population (referred to as the Per-Protocol Set), included 27,817 subjects who received two doses (at 0 and 1 month) of either Moderna COVID-19 Vaccine ( $n=13,934$ ) or placebo ( $n=13,883$ ), had a negative baseline SARS-CoV-2 status, and did not develop confirmed COVID-19 within 14 days after the second dose. The study population was 52.6% male, 20% Hispanic or Latino, and 9.7% African American. The median age of subjects was 53 years (range 18-95). Of the study participants, 26.3% 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).

COVID-19 was defined based on the following criteria: The participant must have experienced at least two of the following systemic symptoms: fever ( $\geq 38^{\circ}\text{C}$ ), 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 confirmed by Polymerase Chain Reaction (PCR) and by a Clinical Adjudication Committee.

An interim analysis was conducted on confirmed COVID-19 cases starting 14 days after Dose 2 of Moderna COVID-19 Vaccine or placebo ([Table 2](#)).

**Table 2: Interim Primary Efficacy Analysis: Confirmed COVID-19\* Regardless of Severity Starting 14 Days After Dose 2 – Per-Protocol Set**

Age Group (Years)	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI) <sup>†</sup>
	Subjects (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Subjects (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
<b>Overall (≥18)</b>	13,934	5	1.840	13,883	90	33.365	94.5 (86.5, 97.8) <sup>‡</sup>
<b>18 to &lt;65</b>	10,407	5	2.504	10,384	75	37.788	93.4 (83.7, 97.3)
<b>≥65</b>	3,527	0	--	3,499	15	21.046	100

\* 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.

<sup>†</sup> VE and 95% CI from the stratified Cox proportional hazard model

<sup>‡</sup> The one-sided p-value is <0.0001 from the stratified Cox proportional hazard model to test the null hypothesis of VE ≤30%, achieving the pre-specified efficacy boundary: the one-sided nominal alpha of 0.0049 based on 95 cases using the Lan-DeMets O'Brien-Fleming spending function.

### Efficacy Against Severe COVID-19

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 subjects in the Per-Protocol Set interim analysis, no cases of severe COVID-19 were reported in the Moderna COVID-19 Vaccine group compared with 11 cases reported in the placebo group (incidence rate 4.072 per 1,000 person-years). Vaccine efficacy against severe COVID-19 was 100%.

### Additional Efficacy Analyses

An interim subgroup analysis was conducted on confirmed COVID-19 cases starting 14 days after Dose 2 of Moderna COVID-19 Vaccine or placebo in high-risk subjects, females, and males (Table 3).

**Table 3: Interim Subgroup Analyses of Vaccine Efficacy: COVID-19 Cases 14 Days After Dose 2 per Adjudication Committee Assessments (Primary Efficacy Analysis Set) – Per-Protocol Set**

Subgroup	Moderna COVID-19 Vaccine			Placebo			% Vaccine Efficacy (95% CI) <sup>†</sup>
	Subjects (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	Subjects (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 per 1,000 Person-Years	
<b>Overall high risk*</b>	3,116	1	1.604	3,075	24	39.177	95.9 (69.7, 99.4)
<b>High risk* 18 to &lt;65</b>	2,098	1	2.428	2,061	18	44.673	94.6 (59.4, 99.3)
<b>Not high risk* 18 to &lt;65</b>	8,309	4	2.524	8,323	57	36.034	93.0 (80.8, 97.5)
<b>Females</b>	6,661	3	2.271	6,514	45	34.991	93.5 (79.2, 98.0)
<b>Males</b>	7,273	2	1.433	7,369	45	31.883	95.5 (81.5, 98.9)

\* Subjects 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

<sup>†</sup> VE and 95% CI from the stratified Cox proportional hazard model

## 14 HOW SUPPLIED/STORAGE AND HANDLING

Moderna COVID-19 Vaccine is supplied as a multiple-dose vial containing a maximum of 10 doses of 0.5 mL each.

Each carton of Moderna COVID-19 Vaccine contains 10 multiple-dose vials (NDC 80777-273-99).

Store frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light. Do not store on dry ice or below -40°C (-40°F).

Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use. Do not refreeze.

Unopened vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours. Do not refreeze.

After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze.

## 15 PATIENT COUNSELING INFORMATION

See Fact Sheet for Recipients and Caregivers

## **16 CONTACT INFORMATION**

If you have questions, please contact:

Moderna

1-866-MODERNA (1-866-663-3762)

medinfo@modernatx.com

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Patent(s): [www.modernatx.com/patents](http://www.modernatx.com/patents)

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