INTRODUCING mNEXSPIKE®

# A New and Different COVID-19 Vaccine[1]

mNEXSPIKE®
COVID-19 Vaccine, mRNA

## mNEXSPIKE is designed to be different from Spikevax® (COVID-19 Vaccine, mRNA)[1,2]

mNEXSPIKE encodes immunodominant epitopes of the COVID-19 spike protein, thus incorporating a smaller mRNA molecule compared with Spikevax, which encodes for the entire spike protein[1,3]

**LOWER DOSE**
**1/5**
that of Spikevax
(10 µg vs 50 µg)[1,2]

**SMALLER VOLUME**
**0.2 mL**
vs 0.5 mL
for Spikevax[1,2]

## mNEXSPIKE demonstrated a numerically higher rVE against COVID-19 vs Spikevax in a phase 3 noninferiority trial[1]*

- **11,366 vaccine-experienced participants aged ≥12 years** received either **mNEXSPIKE (n=5679)** or **Spikevax (n=5687)**
- **Primary efficacy objective: noninferior vaccine efficacy against COVID-19** starting 14 days after mNEXSPIKE compared with that after Spikevax

Higher antibody response and seroresponse rate led to a **greater immune response** compared with Spikevax.†

**Clinical study of mNEXSPIKE was not designed to evaluate superiority.**

**PRIMARY EFFICACY ANALYSIS POPULATION**

**9.3% numerically higher rVE**

against COVID-19‡ vs Spikevax§
(99.4% CI: -6.6, 22.8)

## In a subgroup analysis of adults aged ≥65 years, mNEXSPIKE demonstrated a numerically higher rVE vs Spikevax[1]*

| | ≥65 Years of Age | |
|---|---|---|
| COVID-19 events through January 31, 2024—per-protocol set for efficacy | mNEXSPIKE (10 µg) n=1630 | Spikevax (50 µg) n=1635 |
| **COVID-19 cases** | **149** | **172** |
| **Incidence rate per 100 person-months** | **1.3** | **1.5** |

rVE analyses by subgroups were descriptive without *P*-values.

**Clinical study of mNEXSPIKE was not designed to evaluate superiority.**

**13.5% numerically higher rVE**

against COVID-19‡ vs Spikevax
(95% CI: -7.7, 30.6)

*Participants had previously received at least one dose of a COVID-19 vaccine prior to the study. †Co-primary immunogenicity endpoints: At Day 29, the mNEXSPIKE to Spikevax GMC ratio (95% CI) was 1.3 (1.2, 1.5), and the seroresponse rate difference (95% CI) was 14.4% (9.3, 19.4). mNEXSPIKE met the pre-specified noninferiority criterion of the lower bound of the 95% CI of GMC ratio >0.667, and the pre-specified noninferiority criterion of the lower bound of the 95% CI of the SRR-difference >-10%. ‡Presence of at least 1 symptom from a list of COVID-19 symptoms and a positive NP swab for SARS-CoV-2 by RT-PCR. Listed symptoms were fever (temperature ≥38 °C/≥100.4 °F) or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea. §Success criteria were defined as lower bound of 2-sided 99.4% (alpha-adjusted) CI of rVE >-10% (2-sided alpha spending function: 0.0028).

## INDICATION

mNEXSPIKE® (COVID-19 Vaccine, mRNA) is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

mNEXSPIKE is approved for use in individuals who are:

- 65 years of age and older, or
- 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

## IMPORTANT SAFETY INFORMATION

### Contraindications

Do not administer mNEXSPIKE® to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of mNEXSPIKE or to individuals who had a severe allergic reaction following a previous dose of SPIKEVAX (COVID-19 Vaccine, mRNA) or any Moderna COVID-19 vaccine authorized for emergency use.

**Please see accompanying Full Prescribing Information.**

## mNEXSPIKE rVE across individuals with at least 1 CDC-defined high-risk condition* for severe COVID-19 was studied in a post hoc analysis[4,5†]

| | | mNEXSPIKE (10 µg) | Spikevax® (50 µg) |
|---|---|---|---|
| | rVE based on HR (95% CI) | Participants with COVID-19,‡ % [n/N] | |
| **≥1 comorbidities** in all participants 12 years of age and older | **16.3%** (1.8, 28.7) | 10.2% (274/2674) | 12.3% (334/2725) |
| **And ≥50 years of age** with ≥1 comorbidities | **21.3%** (4.3, 35.3) | 9.7% (176/1811) | 12.3% (233/1895) |
| **And ≥65 years of age** with ≥1 comorbidities | **28.1%** (4.4, 45.9) | 8.6% (81/947) | 11.7% (114/971) |

**Analysis Limitation:** This endpoint was not powered for statistical analysis and should be considered descriptive only. Therefore, results require cautious interpretation and could represent chance findings. These data are not included in the mNEXSPIKE prescribing information.

*CDC-defined high-risk condition for severe COVID-19: https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html †Participants had previously received at least one dose of a COVID-19 vaccine prior to the study. ‡Presence of at least one symptom from a list of COVID-19 symptoms and a positive NP swab for SARS-CoV-2 by RT-PCR.

## mNEXSPIKE demonstrated a safety profile comparable with Spikevax[1]

**Most commonly (≥10%) reported adverse reactions within 7 days[§] after administration of mNEXSPIKE vs Spikevax:**

| | |
|---|---|
| **12-17 years of age** | Pain at the injection site (68.8% vs 78.8%), headache (54.5% vs 58.0%), fatigue (47.3% vs 50.7%), myalgia (39.2% vs 36.0%), axillary swelling or tenderness (34.6% vs 27.1%), chills (31.6% vs 31.9%), arthralgia (23.9% vs 23.6%), and nausea/vomiting (16.1% vs 17.6%) |
| **18-64 years of age** | Pain at the injection site (74.8% vs 81.7%), fatigue (54.3% vs 52.5%), headache (47.8% vs 44.3%), myalgia (41.6% vs 41.1%), arthralgia (32.4% vs 30.6%), chills (24.3% vs 21.3%), axillary swelling or tenderness (21.7% vs 21.0%), and nausea/vomiting (13.8% vs 11.9%) |
| **65 years of age and older** | Pain at the injection site (54.6% vs 67.7%), fatigue (43.0% vs 41.0%), headache (33.1% vs 29.3%), myalgia (30.5% vs 28.5%), arthralgia (25.6% vs 22.4%), chills (16.5% vs 12.8%), and axillary swelling or tenderness (10.7% vs 10.0%) |

**mNEXSPIKE showed generally fewer local adverse reactions for patients 65 years of age and older**

§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).

Recommend mNEXSPIKE, a new and different COVID-19 vaccine[1]

## mNEXSPIKE Storage and Handling[1]

- Store frozen between -40 °F to 5 °F (-40 °C to -15 °C)
- During storage and after thawing, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light
- After thawing, mNEXSPIKE may be stored refrigerated between 36 °F to 46 °F (2 °C to 8 °C) for up to 90 days or up to the expiration date printed on the carton, whichever comes first
- After thawing, mNEXSPIKE may be stored between 46 °F to 77 °F (8 °C to 25 °C) for up to 24 hours
- After thawing, do not refreeze. Do not shake. Thawed syringes can be handled in room light conditions

## IMPORTANT SAFETY INFORMATION (cont.)

### Warnings and Precautions

- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of mNEXSPIKE.
- **Myocarditis and Pericarditis:** Postmarketing data with authorized or approved mRNA COVID-19 vaccines have demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age.
- **Syncope (fainting):** May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- **Altered Immunocompetence:** Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to mNEXSPIKE.
- **Limitations of Vaccine Effectiveness:** mNEXSPIKE may not protect all vaccine recipients.

### Adverse Reactions

The most commonly reported (≥10%) adverse reactions were pain at the injection site, fatigue, headache, myalgia, chills, arthralgia, axillary swelling or tenderness, and nausea/vomiting.

Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov or by calling 1-800-822-7967.

**For Colorado and Connecticut price disclosure, please visit https://modernadirect.com/wac-disclosure.**

**Please see accompanying Full Prescribing Information.**

**Learn more at mNEXSPIKEpro.com.**

CDC, Centers for Disease Control and Prevention; COVID-19, coronavirus disease 2019; GMC, geometric mean concentration; HR, hazard ratio; mRNA, messenger RNA; NP, nasopharyngeal; RT-PCR, reverse transcription polymerase chain reaction; rVE, relative vaccine efficacy; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SRR, seroresponse rate.

**References: 1.** mNEXSPIKE Prescribing Information. Moderna; 2025. **2.** Spikevax Prescribing Information. Moderna; 2025. **3.** Chalkias S, et al. *J Infect Dis*. 2025;231(4):e754-e763. **4.** Chalkias S, et al. *Lancet Infect Dis*. Published online July 7, 2025. doi:10.1016/S1473-3099(25)00236-1 **5.** CDC. Accessed August 27, 2025. https://www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html



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