A Different COVID-19 Vaccine—High Protection in a Lower Dose[1–3]

mNEXSPIKE®
COVID-19 Vaccine, mRNA

mNEXSPIKE® demonstrated numerically higher rVE against COVID-19 vs Spikevax® (COVID-19 Vaccine, mRNA) in a phase 3 noninferiority trial[1]*

PRIMARY EFFICACY ANALYSIS

- **Population: 11,336 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 (10 µg dose) compared with that after Spikevax (50 µg dose)
- **Primary immunogenicity objective: noninferior neutralizing antibody response** starting 29 days after mNEXSPIKE (n=621) compared with that after Spikevax (n=568)†

9.3%
numerically higher rVE
against COVID-19‡
vs Spikevax§
(99.4% CI: -6.6, 22.8)

SUBGROUP ANALYSIS OF ADULTS AGED 65+

(mNEXSPIKE n=1630; Spikevax n=1635)

13.5%
numerically higher rVE
against COVID-19‡
vs Spikevax¶
(95% CI: -7.7, 30.6)
rVE analyses by subgroups were descriptive without *P-values*.

(mNEXSPIKE n=152; Spikevax n=159)

NEARLY 2x
higher immune response rate
vs Spikevax†#**††
GMR (95% CI): 1.8 (1.4, 2.2)
This endpoint should be considered descriptive only. Results require cautious interpretation and could represent chance findings.

Clinical study of mNEXSPIKE was not designed to evaluate superiority.

*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 GMR (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 GMR >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 criterion was defined as lower bound of 2-sided 99.4% (alpha-adjusted) CI of rVE >-10% (2-sided alpha spending function: 0.0028). ¶rVE (95% CI) for 18–64-year age group (mNEXSPIKE n=3558; Spikevax n=3562): 9.7% (-3.8%, 21.3%). rVE (95% CI) for 12–17-year age group (mNEXSPIKE n=491; Spikevax n=490): -29.2% (-123.3%, 25.3%). #Study 301 per-protocol immunogenicity set. **Against Omicron (BA.4/BA.5) compared to Spikevax. ††GMR (95% CI) for 18–64-year age group (mNEXSPIKE n=378; Spikevax n=316): 1.3 (1.1, 1.5). GMR (95% CI) for 12–17-year age group (mNEXSPIKE n=91; Spikevax n=93): 1.0 (0.8, 1.3).

mNEXSPIKE rVE vs Spikevax 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	Spikevax
	rVE based on HR (95% CI)	Participants with COVID-19, % (n/N)	
≥1 comorbidities in all participants ≥12 years of age	**16.3%** (1.8, 28.7)	10.2% (274/2674)	12.3% (334/2725)
≥50 years of age with ≥1 comorbidities	**21.3%** (4.3, 35.3)	9.7% (176/1811)	12.3% (233/1895)
≥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. Not all CDC-listed risk groups were represented in the study population; exclusion criteria included chronic diseases requiring ongoing medical intervention within 2 months before enrollment, immunocompromising conditions or medications, and any malignancy within 5 years of screening. §§Based on COVID-19 events through January 31, 2024.

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 continued IMPORTANT SAFETY INFORMATION on the back page and accompanying Full Prescribing Information.

UPDATED FOR THE 2026–2027 SEASON[1]

Protect Your High-Risk Patients With mNEXSPIKE[1,5,6*†]

mNEXSPIKE®
COVID-19 Vaccine, mRNA

Why Your Recommendation Matters

Older adults are at the **highest risk** for severe COVID-19 outcomes, including hospitalization and death[5]

Patients with comorbidities were **30% to 80%** more likely to develop **severe COVID-19** than those without[7‡]

Why mNEXSPIKE

mNEXSPIKE provides a **robust immune response at a lower dose** compared with Spikevax, with similar side effects[1–3]

Refrigerator-Stable Formulation

Store mNEXSPIKE **refrigerated** between 36 °F to 46 °F (2 °C to 8 °C)[1§]

Ready-to-use pre-filled syringe, no reconstitution required[1]

***The CDC recommends COVID-19 vaccines based on individual-based decision-making.[6]** †Children and adolescents (including those ≥12 years of age) with ≥1 underlying condition are at high risk for severe COVID-19 outcomes. Select underlying conditions include medical complexity, genetic, neurologic, and metabolic conditions, congenital heart disease, obesity, diabetes, asthma or chronic lung disease, sickle cell disease, and immunocompromised status.[5] Risk for severe COVID-19 outcomes in adults increases with age and presence of ≥1 underlying conditions. Select underlying conditions include cancer, cerebrovascular disease, chronic kidney disease, chronic liver diseases, chronic lung diseases, diabetes type 1 and 2, heart conditions, and overweight or obesity.[5] ‡From a meta-analysis of 72 observational studies published between January 2022 and March 2024. The studies included participants of all ages who had at least one of the following comorbidities: cardiovascular/cerebrovascular disease, chronic lung conditions, diabetes, and obesity. The meta-analyses were performed for the risks of death, hospitalization, ICU admission, and the combined outcome for the comorbid populations, using the most adjusted reported outcome estimates.[7] §Do not freeze. After removal from refrigerated conditions, mNEXSPIKE can be stored up to 12 hours between 46 °F to 77 °F (8 °C to 25 °C). During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Do not use after the expiration date shown on the label.[1]

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%), 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%), nausea/vomiting (13.8% vs 11.9%)
≥65 years of age	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%), 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).

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.

CDC, Centers for Disease Control and Prevention; COVID-19, coronavirus disease 2019; GMR, geometric mean ratio; ICU, intensive care unit; mRNA, messenger mRNA; 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; 2026. **2.** Spikevax Prescribing Information. Moderna; 2026. **3.** Chalkias S, et al. *J Infect Dis*. 2025;231(4):e754-e763. **4.** Chalkias S, et al. *Lancet Infect Dis*. 2025;25(11):1230-1242. **5.** CDC. Accessed July 27, 2026. https://www.cdc.gov/covid/risk-factors/index.html **6.** CDC. Accessed July 27, 2026. https://www.cdc.gov/covid/hcp/vaccine-considerations/routine-guidance.html **7.** Chapman A, et al. *Int J Infect Dis*. 2025;158:107958.

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