INTRODUCING mNEXSPIKE®

An Enhanced COVID-19 Vaccine for Patients at Risk[1–8]

mNEXSPIKE®
COVID-19 Vaccine, mRNA

Next-generation mNEXSPIKE is different from the comparator vaccine[1,4–6,9]

mNEXSPIKE encodes immunodominant epitopes of the COVID-19 spike protein, thus incorporating a smaller mRNA molecule compared to Spikevax, which encodes for the entire spike protein[1,4]

LOWER DOSE
1/5
that of Spikevax (10 µg vs 50 µg)[1,6]

SMALLER VOLUME
0.2 mL
vs 0.5 mL dose for Spikevax[1,6]

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

- **11,366 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 responses and seroresponse rates leading to a **greater immune response** compared with Spikevax

Clinical study of mNEXSPIKE was not designed to evaluate superiority.

PRIMARY EFFICACY ANALYSIS POPULATION

9.3%
increase in rVE against COVID-19* vs Spikevax†
(99.4% CI: -6.6, 22.8)

In a subgroup analysis of adults aged 65 years and older, mNEXSPIKE demonstrated increased 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.

SUBGROUP ANALYSIS IN ADULTS AGED 65 YEARS AND OLDER

13.5%
increase in rVE against COVID-19* vs Spikevax
(95% CI: -7.7, 30.6)

*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 was defined as lower bound of 2-sided 99.4% (alpha-adjusted) CI of rVE >-10% (2-sided alpha spending function: 0.0028).

mNEXSPIKE rVE across individuals with comorbidities was studied in a post hoc analysis[7,8]

		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	**17.5%** (3.0, 29.8)	10.2% (267/2617)	12.4% (329/2658)
And ≥50 years of age with ≥1 comorbidities	**23.0%** (6.1, 36.9)	9.6% (169/1755)	12.4% (228/1833)
And ≥65 years of age with ≥1 comorbidities	**28.6%** (4.6, 46.6)	8.5% (78/913)	11.8% (110/929)

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.

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, an enhanced COVID-19 vaccine for patients at risk[1–8]

mNEXSPIKE Storage and Handling[1]

- Store frozen between -40 °C to -15 °C (-40 °F to 5 °F).
- 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 2 °C to 8 °C (36 °F to 46 °F) 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 8 °C to 25 °C (46 °F to 77 °F) for up to 24 hours.
- Do not refreeze once thawed. Thawed syringes can be handled in room light conditions.

INDICATION

mNEXSPIKE 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 have been previously vaccinated with any COVID-19 vaccine and 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.

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 click for mNEXSPIKE Full Prescribing Information.

Scan or click to learn more about mNEXSPIKE

COVID-19, coronavirus disease 2019; 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.

References: 1. mNEXSPIKE Prescribing Information. Moderna; 2025. **2.** Allen JC, et al. *Vaccine*. 2020;38(52):8264-8272. **3.** Andrew MK, et al. *Clin Interv Aging*. 2021;16:731-738. **4.** Chalkias S, et al. *J Infect Dis*. 2025;231(4):e754-e763. **5.** Montgomerie I, et al. *iScience*. 2023;26(4):106256. **6.** Spikevax Prescribing Information. Moderna; 2025. **7.** Chalkias S. Efficacy, immunogenicity, and safety of a next-generation mRNA-1283 COVID-19 vaccine compared with the mRNA-1273 vaccine: results from NextCOVE, a phase 3, randomized, observer-blind, active-controlled trial. 2025. Supplementary appendix. **8.** CDC. Accessed May 9, 2025. https://www.cdc.gov/covid/risk-factors/index.html **9.** Chaudhary N, et al. *Nat Rev Drug Discov*. 2021;20(11):817-838.

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mNEXSPIKE® by moderna
COVID-19 Vaccine, mRNA