Product Summary

Now approved

mNEXSPIKE®
COVID-19 Vaccine, mRNA

INDICATIONS AND USAGE

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.

DOSAGE AND ADMINISTRATION

- For intramuscular use.
- Administer mNEXSPIKE as a single 0.2 mL dose at least 3 months after the last dose of COVID-19 vaccine.

DOSAGE FORMS AND STRENGTHS

mNEXSPIKE is an injectable suspension.

A single dose is 0.2 mL.

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 (e.g., anaphylaxis) following a previous dose of SPIKEVAX (COVID-19 Vaccine, mRNA) or any Moderna COVID-19 vaccine authorized for emergency use.

WARNINGS AND PRECAUTIONS

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.

ADVERSE REACTIONS

Most commonly reported adverse reactions following administration of mNEXSPIKE (≥10%):

- *Participants 12 years through 17 years of age:* pain at the injection site (68.8%), headache (54.5%), fatigue (47.3%), myalgia (39.2%), axillary swelling or tenderness (34.6%), chills (31.6%), arthralgia (23.9%), and nausea/vomiting (16.1%).
- *Participants 18 years through 64 years of age:* pain at the injection site (74.8%), fatigue (54.3%), headache (47.8%), myalgia (41.6%), arthralgia (32.4%), chills (24.3%), axillary swelling or tenderness (21.7%), and nausea/vomiting (13.8%).
- *Participants 65 years of age and older:* pain at the injection site (54.6%), fatigue (43.0%), headache (33.1%), myalgia (30.5%), arthralgia (25.6%), chills (16.5%), and axillary swelling or tenderness (10.7%).

Safety results: local and systemic adverse reactions

	12 to 17 years		18 to 64 years		≥65 years	
	mNEXSPIKE[a] N=497 n (%)	Comparator Vaccine[b] N=495 n (%)	mNEXSPIKE[a] N=3573 n (%)	Comparator Vaccine[b] N=3574 n (%)	mNEXSPIKE[a] N=1632 n (%)	Comparator Vaccine[b] N=1637 n (%)
Local adverse reactions[c]						
Pain[d]	342 (68.8)	390 (78.8)	2672 (74.8)	2920 (81.7)	891 (54.6)	1109 (67.7)
Axillary swelling or tenderness[d]	172 (34.6)	134 (27.1)	777 (21.7)	749 (21.0)	174 (10.7)	164 (10.0)
Swelling (hardness) ≥25 mm[e]	18 (3.6)	25 (5.1)	140 (3.9)	246 (6.9)	48 (2.9)	88 (5.4)
Erythema (redness) ≥25 mm[e]	6 (1.2)	13 (2.6)	85 (2.4)	152 (4.3)	32 (2.0)	60 (3.7)
Systemic adverse reactions[f]						
Headache[g]	271 (54.5)	287 (58.0)	1708 (47.8)	1583 (44.3)	540 (33.1)	479 (29.3)
Fatigue[g]	235 (47.3)	251 (50.7)	1939 (54.3)	1876 (52.5)	702 (43.0)	671 (41.0)
Myalgia[g]	195 (39.2)	178 (36.0)	1485 (41.6)	1469 (41.1)	498 (30.5)	467 (28.5)
Chills[h]	157 (31.6)	158 (31.9)	867 (24.3)	760 (21.3)	269 (16.5)	209 (12.8)
Arthralgia[g]	119 (23.9)	117 (23.6)	1159 (32.4)	1094 (30.6)	418 (25.6)	366 (22.4)
Nausea/vomiting[i]	80 (16.1)	87 (17.6)	492 (13.8)	424 (11.9)	119 (7.3)	114 (7.0)
Fever[j]	49 (9.9)	46 (9.3)	193 (5.4)	138 (3.9)	75 (4.6)	70 (4.3)
Use of antipyretic or pain medication	186 (37.4)	211 (42.6)	1243 (34.8)	1226 (34.3)	429 (26.3)	393 (24.0)

N=Number of participants in the solicited safety set; n=Number of participants with listed solicited adverse reactions.

[a]A vaccine encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5. [b]Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). [c]Solicited local adverse reactions starting within 7 days after injection (solicited safety set); 7 days included day of vaccination and the subsequent 6 days. Events were collected in the electronic diary (e-diary). [d]Pain and axillary swelling or tenderness grading scale: no interference with activity (Grade 1); some interference with activity (Grade 2); prevents daily activity (Grade 3). [e]Swelling and erythema grading scale: 25-50 mm / 2.5-5 cm (Grade 1); 51-100 mm / 5.1-10 cm (Grade 2); >100 mm / >10 cm (Grade 3). [f]Solicited systemic adverse reactions starting within 7 days after injection in participants 12 years through 17 years (solicited safety set); 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). [g]Headache, fatigue, myalgia, arthralgia grading scale: no interference with activity (Grade 1); some interference with activity (Grade 2); prevents daily activity (Grade 3). [h]Chills grading scale: no interference with activity (Grade 1); some interference with activity not requiring medical intervention (Grade 2); prevents daily activity and requires medical intervention (Grade 3). [i]Nausea/vomiting grading scale: no interference with activity or 1-2 episodes/24 hours (Grade 1); some interference with activity or >2 episodes/24 hours (Grade 2); prevents daily activity, requires outpatient intravenous hydration (Grade 3). [j]Fever grading scale: ≥38.0 ° – ≤38.4 °C / ≥100.4 ° – ≤101.1 °F (Grade 1); ≥38.5 ° – ≤38.9 °C / ≥101.2 °– ≤102.0 °F (Grade 2); ≥39.0 ° – ≤40.0 °C / ≥102.1 ° – ≤104.0 °F (Grade 3).

Study design and relative vaccine efficacy

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A phase 3 randomized, observer-blind, active-controlled clinical trial evaluated the relative vaccine efficacy, safety, and immunogenicity of mNEXSPIKE in participants 12 years of age and older in the United States, United Kingdom, and Canada.

The primary efficacy analysis population (referred to as the Per-Protocol Set for Efficacy) included 11,366 participants who received either mNEXSPIKE (n=5,679) or Moderna COVID-19 Vaccine, Bivalent (n=5,687).

The primary efficacy objective in this study was to demonstrate the non-inferior vaccine efficacy against COVID-19 starting 14 days after mNEXSPIKE compared to that after the comparator vaccine.

Relative vaccine efficacy against COVID-19* in participants 12 years of age and older starting 14 days after a single dose of mNEXSPIKE or comparator vaccine – per-protocol set for efficacy

mNEXSPIKE[a]			Comparator Vaccine[b]			
Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 Per 100 Person-Months[c]	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 Per 100 Person-Months[c]	Relative Vaccine Efficacy (99.4% CI)[d]
5,679	560	1.4	5,687	617	1.5	9.3% (-6.6%, 22.8%)[e]

*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. 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. [a]A vaccine encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5. [b]Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). [c]Person-months is defined as the total months from study injection date to the date of event (COVID-19), date of off-study COVID-19 vaccine, last date of study participation, death date or efficacy data cutoff date, whichever is the earliest. [d]Relative Vaccine Efficacy (rVE) = 1-hazard ratio (mNEXSPIKE vs comparator vaccine). Hazard ratio and CI are estimated using a stratified Cox proportional hazard model (stratified by age group per randomization) with Efron's method of tie handling and with the treatment group as a fixed effect. Alpha-adjusted 2-sided (99.4%) confidence level is calculated using Lan-DeMets O'Brien-Fleming spending function (nominal one-sided alpha = 0.0028). [e]The success criterion for the primary efficacy endpoint was that the lower limit of the 2-sided CI for rVE was >-10%.

Descriptive analysis of incidence of COVID-19* in participants 12 years of age and older by age subgroup starting 14 days after a single dose of mNEXSPIKE or comparator vaccine – per-protocol set for efficacy

mNEXSPIKE[a]				Comparator Vaccine[b]			
Age Subgroup (Years)	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 Per 100 Person-Months[c]	Participants (N)	COVID-19 Cases (n)	Incidence Rate of COVID-19 Per 100 Person-Months[c]	Descriptive rVE[d] (95% CI)[e]
12 to <18	491	29	1.0	490	23	0.8	-29.2%[f] (-123.3%, 25.3%)
18 to <65	3,558	382	1.4	3,562	422	1.6	9.7% (-3.8%, 21.3%)
≥65	1,630	149	1.3	1,635	172	1.5	13.5% (-7.7%, 30.6%)

*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. 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. [a]A vaccine encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5. [b]Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). [c]Person-months is defined as the total months from study injection date to the date of event (COVID-19), date of off-study COVID-19 vaccine, last date of study participation, death date or efficacy data cutoff date, whichever is the earliest. [d]rVE=relative vaccine efficacy. [e]Descriptive relative vaccine efficacy means that these endpoints were not hypothesis-tested and do not necessarily make valid inferences about vaccine efficacy. [f]VE cannot be reliably estimated due to the low number of cases accrued in this age group.

Immunogenicity

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The primary immunogenicity analysis population included 621 participants who received mNEXSPIKE and 568 participants who received the comparator vaccine.

The primary immunogenicity analyses evaluated the ratio of neutralizing antibody geometric mean concentrations (GMC) and the difference in seroresponse rate (SRR) against a pseudovirus expressing Omicron BA.4/BA.5 and the original SARS-CoV-2 Spike protein (D614G) following vaccination with mNEXSPIKE compared to vaccination with the comparator vaccine.

Comparison of geometric mean concentration 28 days after a single dose of mNEXSPIKE vs 28 days after a single dose of comparator vaccine – per-protocol immunogenicity subset*

Assay	mNEXSPIKE[a] GMC N=621 (95% CI)[b]	Comparator Vaccine[c] GMC N=568 (95% CI)[b]	GMC Ratio (mNEXSPIKE/ Comparator Vaccine) (95% CI)[b]
Omicron BA.4/BA.5	2340.9 (2167.0, 2528.8)	1753.8 (1618.2, 1900.7)	1.3 (1.2, 1.5)

GMC=Geometric Mean Concentration

N=Number of participants with non-missing data at the corresponding timepoint(s).

*Per-Protocol Immunogenicity Subset included a randomly selected subset of subjects (Immunogenicity Subset) who received study vaccine, and did not have a major protocol deviation that impacted immune response and had both pre-dose and post-dose immunogenicity assessment at timepoint of primary interest (28 days post-dose). [a]A vaccine encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5. [b]The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the group variable (mNEXSPIKE vs comparator vaccine) as fixed effect, adjusted by SARS-CoV-2 infection status at baseline, randomization age group, number of prior COVID-19 boosters (0, 1, 2, ≥3), and type of last prior COVID-19 vaccine. Coefficients for Least Square Means use margins by level. The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation. [c]Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5).

Note: Antibody values < the lower limit of quantitation (LLOQ) are replaced by 0.5 × LLOQ. Values > the upper limit of quantitation (ULOQ) are replaced by the ULOQ if actual values are not available.

Descriptive analysis of geometric mean concentration by age subgroup 28 days after a single dose of mNEXSPIKE vs 28 days after a single dose of comparator vaccine – per-protocol immunogenicity subset*

Assay	Age Subgroup (Years)	mNEXSPIKE[a] GMC N=621 (95% CI)[b]	Comparator Vaccine[c] GMC N=568 (95% CI)[b]	GMC Ratio (mNEXSPIKE/ Comparator Vaccine) (95% CI)[b]
Omicron BA.4/BA.5	12 to <18	N=91 3561.4 (3037.5, 4175.7)	N=93 3398.9 (2908.9, 3971.4)	1.0 (0.8, 1.3)
	18 to <65	N=378 2120.6 (1917.3, 2345.6)	N=316 1661.0 (1487.8, 1854.4)	1.3 (1.1, 1.5)
	≥65	N=152 2339.5 (1984.3, 2758.3)	N=159 1326.8 (1130.0, 1557.7)	1.8 (1.4, 2.2)

GMC=Geometric Mean Concentration

N=Number of participants in the corresponding age group.

*Per-Protocol Immunogenicity Subset included a randomly selected subset of subjects (Immunogenicity Subset) who received study vaccine, and did not have a major protocol deviation that impacted immune response and had both pre-dose and post-dose immunogenicity assessment at timepoint of primary interest (28 days post-dose). [a]A vaccine encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5. [b]The log-transformed antibody levels are analyzed using an analysis of covariance (ANCOVA) model with the group variable (mNEXSPIKE vs comparator vaccine) as fixed effect, adjusted by SARS-CoV-2 infection status at baseline, number of prior COVID-19 boosters (0, 1, 2, ≥3), and type of last prior COVID-19 vaccine. Coefficients for Least Square Means use margins by level. The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation. [c]Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5).

Note: Antibody values < the lower limit of quantitation (LLOQ) are replaced by 0.5 × LLOQ. Values > the upper limit of quantitation (ULOQ) are replaced by the ULOQ if actual values are not available.

Immunogenicity (cont.)

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Comparison of seroresponse rate 28 days after a single dose of mNEXSPIKE vs 28 days after a single dose of comparator vaccine – per-protocol immunogenicity subset*

Assay	mNEXSPIKE[a] Seroresponse Rate[b] N=621 % (95% CI)[c]	Comparator Vaccine[d] Seroresponse Rate[b] N=568 % (95% CI)[c]	Difference in Seroresponse Rate (mNEXSPIKE-Comparator Vaccine) % (95% CI)[e]
Omicron BA.4/BA.5	79.9 (76.5, 83.0)	65.5 (61.4, 69.4)	14.4 (9.3, 19.4)

N=Number of participants with non-missing data at the corresponding timepoint(s).

*Per-Protocol Immunogenicity Subset included a randomly selected subset of subjects (Immunogenicity Subset) who received study vaccine, and did not have a major protocol deviation that impacted immune response and had both pre-dose and post-dose immunogenicity assessment at timepoint of primary interest (28 days post-dose). [a]A vaccine encoding the membrane-bound, linked NTD and RBD of the S glycoprotein from SARS-CoV-2 Original and Omicron variant lineages BA.4/BA.5. [b]Seroresponse is defined as an antibody value change from baseline below the LLOQ to ≥4 × LLOQ, or at least a 4-fold rise if baseline is ≥ LLOQ and <4 × LLOQ, or at least a 2-fold rise if baseline is ≥4 × LLOQ, where baseline refers to pre-dose. [c]95% CI is calculated using the Clopper-Pearson method. [d]Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). [e]95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.

Storage

- 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.

Scan or click the QR code to learn more about mNEXSPIKE

Scan or click for mNEXSPIKE Full Prescribing Information

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

mRNA, messenger RNA; NP, nasopharyngeal; NTD, N-terminal domain; RBD, receptor-binding domain; RT-PCR, reverse transcription-polymerase chain reaction; S, Spike.

moderna®