



2025–2026 Formula: Product Information Guide

**Protect individuals at high risk for severe outcomes
with a new and different COVID-19 vaccine^{1,2*}**

*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.²

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.²

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 throughout,
and scan or click the QR code on page 6 for [Full Prescribing Information](#).**

moderna®

A New COVID-19 Vaccine for the 2025–2026 Season^{1,3}



For Individuals at High Risk for Severe COVID-19 Outcomes

Adults aged **65 years and older**

Individuals aged **12–64 years with ≥1 underlying condition***
that puts them at high risk for severe outcomes from COVID-19



Designed to Be Different

Lower dose, smaller volume, and improved refrigerator stability
compared with Spikevax® (COVID-19 Vaccine, mRNA)



Flexible Storage Options

mNEXSPIKE can be stored frozen up to expiration date
or thawed in the refrigerator for up to **90 days**

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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.²

IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions

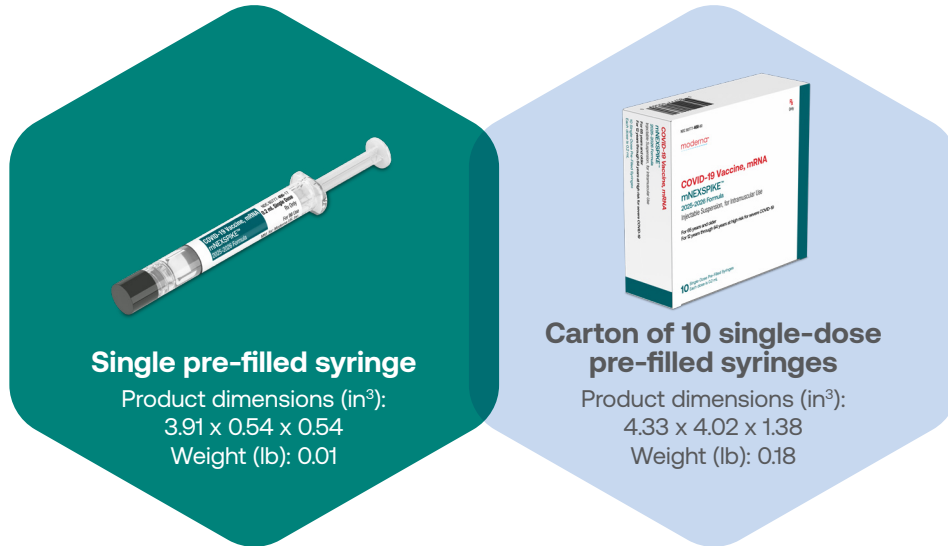
- **Management of Acute Allergic Reactions:** Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of mNEXSPIKE.
- **Myocarditis and Pericarditis:** Postmarketing data with authorized or approved mRNA COVID-19 vaccines have demonstrated 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.

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Available Exclusively as a Pre-filled Syringe¹



Pre-filled syringes are supplied in paperboard tray cartons



Single pre-filled syringe

Product dimensions (in³):
3.91 x 0.54 x 0.54
Weight (lb): 0.01

Carton of 10 single-dose pre-filled syringes

Product dimensions (in³):
4.33 x 4.02 x 1.38
Weight (lb): 0.18



Follow the steps below to properly
remove the mNEXSPIKE tip cap¹

1. Grab the syringe with one hand and grip the tip cap with the other hand
2. With tip cap upright, remove tip cap by twisting counterclockwise until tip cap releases
3. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting
4. Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe
5. Discard after single use

IMPORTANT SAFETY INFORMATION (CONT.)

Warnings and Precautions (Cont.)

- **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.

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Storage, Handling, and Dosing



Guidance on proper preparation of mNEXSPIKE: stock storage to administration¹

Shipped Frozen	Frozen Storage (Stock)*	Thawing From Frozen	Storage After Thawing†	Preparing for Use
	Store frozen at -40 °F to 5 °F (-40 °C to -15 °C)	Refrigeration Thaw Duration: 36 °F to 46 °F (2 °C to 8 °C) • Single syringe (removed from carton): 1 hour and 40 minutes • Carton of 10 syringes: 2 hours and 40 minutes OR Room Temperature Thaw Duration: 59 °F to 77 °F (15 °C to 25 °C) • Single syringe (removed from carton): 40 minutes • Carton of 10 syringes: 1 hour and 20 minutes	Refrigeration: 36 °F to 46 °F (2 °C to 8 °C) <i>Beyond use date: Must not exceed 90 days or up to the carton expiration date, whichever comes first</i> OR Room Temperature: 46 °F to 77 °F (8 °C to 25 °C) <i>Beyond use date: Must not exceed 24 hours</i>	• With tip cap upright, remove tip cap by twisting counterclockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting • Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe • Immunizer should select a needle of appropriate size and gauge for intramuscular injection • Discard after single use

Transportation of Thawed Syringes at 36 °F to 46 °F (2 °C to 8 °C): Thawed pre-filled syringes can be transported at 36 °F to 46 °F (2 °C to 8 °C) in shipping containers qualified to maintain 36 °F to 46 °F (2 °C to 8 °C). Once thawed and transported at 36 °F to 46 °F (2 °C to 8 °C), pre-filled syringes should not be refrozen and should be stored at 36 °F to 46 °F (2 °C to 8 °C) until use, for up to 90 days or carton expiration date, whichever comes first.¹

*During storage and after thawing, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.¹

†After thawing, do not refreeze. Do not shake. Thawed syringes can be handled in room light conditions.¹

mNEXSPIKE is administered intramuscularly as a single 0.2 mL dose¹

Indication	Dose and Schedule
Individuals ≥65 years of age	0.2 mL, single dose If previously vaccinated, administer ≥3 months after the last dose of COVID-19 vaccine
Individuals 12–64 years of age with ≥1 underlying condition that puts them at high risk for severe outcomes from COVID-19	0.2 mL, single dose If previously vaccinated, administer ≥3 months after the last dose of COVID-19 vaccine

IMPORTANT SAFETY INFORMATION (CONT.)

Adverse Reactions

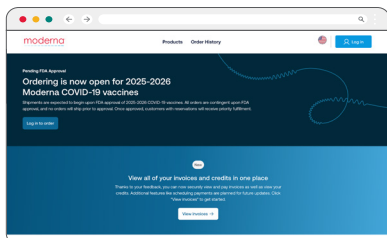
The most commonly reported (≥10%) adverse reactions were pain at the injection site, fatigue, headache, myalgia, chills, arthralgia, axillary swelling or tenderness, and nausea/vomiting.

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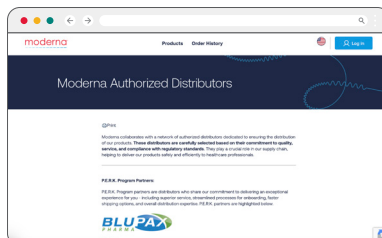
Product Ordering and Billing



Place your order today via Moderna Direct or one of our trusted authorized distributor partners



Scan or click the QR code to **create your Moderna Direct account** or **login** to your existing account.



Scan or click the QR code to learn more about our **authorized distributors**.

Product identification codes¹⁴

Type	Code	Description
NDC	80777-400-60 (10-digit) 80777-0400-60 (11-digit)	Paperboard tray carton of 10 pre-filled syringes
	80777-400-17 (10-digit) 80777-0400-17 (11-digit)	Single-dose pre-filled syringe
CVX	334	SARS-CoV-2 (COVID-19) vaccine, mRNA, spike protein, LNP, preservative free, 10 mcg/0.2 mL dose
MVX	MOD	Moderna

Diagnosis and procedural codes

Type	Code	Description
CPT ^{®4,5*}	91323	Vaccine Product Code Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, 10 mcg/0.2 mL dosage, for intramuscular use
	90480	Vaccine Administration Code Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, single dose
ICD-10-CM ⁶	Z23	Encounter for immunization

*CPT is a registered trademark of the American Medical Association (AMA).

IMPORTANT SAFETY INFORMATION (CONT.)

Adverse Reactions (Cont.)

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.

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



Please scan or click the QR code or ask your representative for Full Prescribing Information.

COVID-19, coronavirus disease 2019; CPT, Current Procedural Terminology; CVX, vaccine administered; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; LNP, lipid nanoparticle; mRNA, messenger RNA; MVX, Manufacturer of Vaccine; NDC, National Drug Code; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

References: 1. mNEXSPIKE Prescribing Information. Moderna; 2025. 2. CDC. Accessed August 27, 2025. <https://www.cdc.gov/covid/risk-factors/index.html> 3. Spikevax Prescribing Information. Moderna; 2025. 4. CDC. Accessed August 4, 2025. <https://www.cdc.gov/iis/code-sets/fall-season-respiratory-codes.html> 5. CMS. Accessed August 4, 2025. <https://www.cms.gov/medicare/payment/covid-19/coding-covid-19-vaccine-shots> 6. ICD10Data.com. 2025 ICD-10-CM Diagnosis code Z23. Accessed July 30, 2025. <https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z29/Z23-/Z23>