mNEXSPIKE (COVID-19 Vaccine, mRNA): A Quick Start Guide

Indications & Usage

mNEXSPIKE is a vaccine indicated for active immunization to prevent COVID-19 caused by 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.

Dosing

mNEXSPIKE is given as a single 0.2 mL dose intramuscularly at least 3 months after the last dose of COVID-19 vaccine.

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 direct sunlight or UV 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.**

Preparation for Administration

- If prefilled syringes of mNEXSPIKE are frozen, thaw before use following the instructions in the table.
- After thawing, do not refreeze.
- Do not administer if vaccine is discolored or contains other particulate matter.
- **Do not shake.**

Item	Thaw in Refrigerator (2°C to 8°C / 36°F to 46°F)	Thaw at Room Temperature (15°C to 25°C / 59°F to 77°F)
Carton of 10 syringes	Thaw for **2 hours and 40 minutes**	Thaw for **1 hour and 20 minutes**
Carton of 2 syringes	Thaw for **1 hour and 40 minutes**	Thaw for **40 minutes**
Carton of 1 syringe	Thaw for **1 hour and 40 minutes**	Thaw for **40 minutes**
One syringe (removed from carton)	Thaw for **1 hour and 40 minutes**	Thaw for **40 minutes**

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.

See next page for continued mNEXSPIKE Important Safety Information and Prescribing Information

Warnings and Precautions *(continued)*

- **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.

Please scan or click the QR code below for mNEXSPIKE Full Prescribing Information: