swissmedic

Date: 18 August 2026
Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

mNEXSPIKE

International non-proprietary name:	SARS-CoV-2 XBB.1.5 mRNA
Pharmaceutical form:	dispersion for injection
Dosage strength(s):	1 dose (0.2 mL) contains 10 micrograms of SARS-CoV-2 mRNA
Route(s) of administration:	intramuscular injection
Marketing authorisation holder:	Moderna Switzerland GmbH
Marketing authorisation no.:	70272
Decision and decision date:	approved on 03.08.2026

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

Table of contents

1 Terms, Definitions, Abbreviations

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
API	Active pharmaceutical ingredient
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	Area under the plasma concentration-time curve for the 24-hour dosing interval
CI	Confidence interval
C_{max}	Maximum observed plasma/serum concentration of drug
CYP	Cytochrome P450
DDI	Drug-drug interaction
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GI	Gastrointestinal
GLP	Good Laboratory Practice
HPLC	High-performance liquid chromatography
IC/EC_{50}	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing authorisation holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Background information on the procedure

2.1 Applicant's request(s) and information regarding procedure

New active substance status
The applicant requested new active substance status for SARS-CoV-2 XBB.1.5 mRNA in the above-mentioned medicinal product.

Authorisation as human medicinal product in accordance with Article 13 TPA
The applicant requested a reduced assessment procedure in accordance with Article 13 TPA.

2.2 Indication and dosage

2.2.1 Requested indication

mNEXSPIKE is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.
The use of this vaccine should be in accordance with official recommendations.

2.2.2 Approved indication

mNEXSPIKE is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.
The use of this vaccine should be in accordance with official recommendations.

2.2.3 Requested dosage

Summary of the requested standard dosage:
The recommended dose of mNEXSPIKE is one single dose of 0.2 mL of the vaccine (10 µg SARS-CoV-2 mRNA).

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	25 February 2026
Formal control completed	25 February 2026
List of Questions (LoQ)	5 June 2026
Response to LoQ	9 June 2026
Preliminary decision	25 June 2026
Response to preliminary decision	2 July 2026
Final decision	3 August 2026
Decision	approval

Based on Art. 13 TPA Swissmedic has not assessed the primary data (e.g. study reports) submitted with this application and relies for its decision on the assessment of the foreign reference authority, the EMA. This SwissPAR relates to the assessment report mNEXSPIKE, EMEA/H/C/006428 (EMA/6890/2026, 04.03.2026) issued by the EMA.

3 Quality aspects

Swissmedic has not assessed the primary data relating to quality aspects submitted with this application and relies on the assessment of the foreign reference authority, the EMA (mNEXSPIKE, EMEA/H/C/006428 (EMA/6890/2026, 04.03.2026) issued by the EMA) (see section 2.3 Regulatory history (milestones)).

4 Nonclinical aspects

Swissmedic has not assessed the primary data relating to nonclinical aspects submitted with this application and relies on the assessment of the foreign reference authority, the EMA (mNEXSPIKE, EMEA/H/C/006428 (EMA/6890/2026, 04.03.2026) issued by the EMA) (see section 2.3 Regulatory history (milestones)).

5 Clinical aspects

Swissmedic has not assessed the primary data relating to clinical (pharmacology) aspects submitted with this application and relies on the assessment of the foreign reference authority, the EMA (mNEXSPIKE, EMEA/H/C/006428 (EMA/6890/2026, 04.03.2026) issued by the EMA) (see section 2.3 Regulatory history (milestones)).

For further information regarding clinical and clinical pharmacology aspects, please refer to the attached Information for healthcare professionals.

6 Risk management plan summary

The RMP summaries contain information on the medicinal products′ safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.
The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

7 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for mNEXSPIKE was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo-pro.ch).

Note:
The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. See the "Undesirable effects" section for advice on the reporting of adverse reactions. The following product information will be regularly updated as soon as new data and safety reports are available.

mNEXSPIKE dispersion for injection in pre-filled syringe

COVID-19 mRNA Vaccine

Composition

Active substances

SARS-CoV-2 mRNA is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA template, encoding the N-terminal domain and receptor-binding domain of the viral spike (S) protein of SARS-CoV-2 (XBB.1.5). The mRNA is embedded in lipid nanoparticles.

Excipients

Heptadecan-9-yl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate (SM-102), cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, sucrose, water for injections.

Pharmaceutical form and active substance quantity per unit

Dispersion for injection in pre-filled syringe
White to off white dispersion (pH: 7.1 – 7.8).

Each single-dose pre-filled syringe contains 0.2 mL.

One dose (0.2 mL) contains 10 µg of SARS-CoV-2 mRNA.

Indications/Uses

mNEXSPIKE is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

Dosage/Administration

This medicinal product should be administered by a trained healthcare professional using aseptic techniques to ensure sterility.

Posology

The recommended dose of mNEXSPIKE is one single dose of 0.2 mL of the vaccine (10 µg SARS-CoV-2 mRNA).

If previously vaccinated with a COVID-19 vaccine, mNEXSPIKE should be administered at the earliest 3 months after the most recent dose of a COVID-19 vaccine (see sections "Warnings and precautions" and "Properties/Effects").

Elderly
No dose adjustment is required in elderly individuals ≥65 years of age.

Paediatric population
The safety and efficacy of mNEXSPIKE in children less than 12 years of age have not yet been established. No data are available.

Method of administration

For intramuscular injection only. The preferred site is the deltoid muscle of the upper arm.

Do not administer this vaccine intravascularly, subcutaneously or intradermally.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

For instructions on preparation of the medicinal product before administration see section “Other information”.

For precautions to be taken before administering the vaccine, see section “Warnings and precautions”.

Traceability
To ensure traceability of biotechnological medicinal products, it is recommended that the trade name and batch number should be documented for each treatment.

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section “Composition”.

Warnings and precautions

Hypersensitivity and anaphylaxis

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Close observation for at least 15 minutes is recommended following vaccination. No further dose of the vaccine should be given to those who have experienced anaphylaxis after a prior dose of the vaccine.

Myocarditis and pericarditis

An increased risk of myocarditis and pericarditis has been observed following vaccination with some other COVID-19 vaccines. These conditions can develop within a few days and primarily occur within 14 days. They have been observed more often in younger males. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccine recipients (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute severe febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

Safety and immunogenicity data on mNEXSPIKE are not available for immunocompromised individuals. Individuals receiving immunosuppressant therapy or patients with immunodeficiency may have a diminished immune response to this vaccine.

Limitations of vaccine effectiveness

As with all vaccines, vaccination with mNEXSPIKE may not protect all vaccine recipients.

Duration of protection

The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials.

Interactions

No interaction studies have been performed.

Concomitant administration of mNEXSPIKE with other vaccines has not been studied.

Pregnancy, lactation

Pregnancy

There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of mNEXSPIKE in pregnant women.
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section “Preclinical data”). As a precautionary measure, it is preferable to avoid the use of mNEXSPIKE during pregnancy.

Lactation

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breast-feeding woman to mNEXSPIKE active substance is negligible. Observational data from women who were breastfeeding after vaccination with elasomeran and its variants have not shown a risk for adverse effects in breastfed newborns/infants.

mNEXSPIKE can be used during breast-feeding.

Fertility

No human data on the effect of mNEXSPIKE on fertility are available.

Animal studies do not indicate direct or indirect harmful effects with respect to female reproductive toxicity. Animal studies conducted with mNEXSPIKE are insufficient to assess functional effects on male reproductive toxicity (see section “Preclinical data”).

Effects on ability to drive and use machines

mNEXSPIKE has no or negligible influence on the ability to drive and use machines.

However, some of the effects mentioned under section “Undesirable effects” (e.g., fatigue) may temporarily affect the ability to drive or use machines.

Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions are injection site pain (68.5%), fatigue (50.4%), headache (44.2%), myalgia (38.2%), arthralgia (29.7%), chills (22.7%), axillary swelling or tenderness (19.7 %) and nausea/vomiting (12.1%).

The following adverse reactions were more common in participants below 18 years of age: pain at the injection site (68.8%), headache (54.5%), myalgia (39.2%), axillary swelling/tenderness (34.6%), chills (31.6%) and nausea/vomiting (16.1%).

Tabulated list of adverse reactions

The safety of mNEXSPIKE was evaluated in a Phase 3 clinical study. Study mRNA-1283-P301 (Study 1) included 11’417 participants 12 years of age and older. The median duration of follow-up for safety was 8.8 months.

The safety profile and the frequencies of adverse reactions presented below are based on data of 5‘706 individuals ≥12 years of age. Age-stratified analysis indicates a trend of decreasing reactogenicity with increasing age.

Adverse reactions reported are listed according to the following frequency convention:

Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1 000 to <1/100)
Rare (≥1/10 000 to <1/1 000)
Very rare (<1/10 000)
Not known (cannot be estimated from the available data)

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness (Table 1).

Table 1. Adverse reactions

MedDRA system organ class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Very common	Lymphadenopathy (ipsilateral axillary swelling or tenderness)
	Rare	Lymphadenopathy (e.g. supraclavicular)
Nervous system disorders	Very common	Headache
	Rare	Hypoaesthesia
Immune system disorders	Uncommon	Hypersensitivity reactions (e.g. urticaria, chronic urticaria, rash, pruritus)
	Not known	Anaphylactic reaction
Gastrointestinal disorders	Very common	Nausea/vomiting
	Rare	Diarrhoea
Skin and subcutaneous tissue disorders	Very rare	Rash
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills
	Common	Pyrexia Injection site swelling Injection site erythema
	Rare	Injection site pruritus Injection site bruising

Paediatric population

Safety data for mNEXSPIKE in adolescents were collected in a Phase 3 randomised, observer-blind, active-controlled clinical trial that 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. In this study, 8.7% (N=992/11’417) of participants were 12 years through 17 years.

The incidence of solicited systemic adverse reactions was similar for the mNEXSPIKE group for the population overall and across all age subgroups. In Study mRNA-1283-P301 (Study 1), assessment of unsolicited adverse events did not reveal any safety concerns for the adolescent population, and no differences of clinical concern were noted between the two vaccine groups or when compared to the adult population.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the EIViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

No cases of overdose have been reported.

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

Properties/Effects

ATC code

J07BN01

Mechanism of action

mNEXSPIKE is a nucleoside-modified mRNA-based vaccine, formulated in lipid particles, which encodes the membrane-bound, linked N-terminal domain (NTD) and receptor-binding domain (RBD) of the spike (S) glycoprotein from SARS-CoV-2 strains. The vaccine elicits an immune response to the NTD and RBD of the S antigen, to generate neutralising antibodies, which contributes to protection against COVID-19.

Clinical efficacy

Study mRNA-1283-P301 (Study 1)

Study mRNA-1283-P301 was a Phase 3 randomised, observer-blind, active-controlled clinical trial that 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. Randomisation was stratified by age: 12 to 17 years, 18 to 64 years, and 65 years of age and older. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalisation for worsening disease during the 2 months before enrolment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 11’454 participants were randomised in a 1:1 ratio to receive mNEXSPIKE (10 µg SARS-CoV-2 mRNA; n=5’728), or elasomeran/davesomeran, the comparator vaccine (50 µg mRNA; n=5‘726). All participants except one in the mNEXSPIKE group had previously received at least one dose of a COVID-19 vaccine prior to the study with a median time of 9.8 months since the last dose. Participants were followed for efficacy and safety for one year.

In Study mRNA-1283-P301, the median age of the safety population was 56 years (range 12-96 years); 8.7% of participants were 12 years through 17 years, 62.6% were 18 years through 64 years, 28.7% were 65 years and older and 5.2% were over 75 years old.. Overall, 45.7% of the participants were male, 54.3% were female, 13.2% were Hispanic or Latino, 82.2% were White, 11.2% were Black or African American, 3.6% were Asian, and 2.4% reported “Other”. Demographic characteristics were similar between participants who received mNEXSPIKE and those who received elasomeran/davesomeran.

The primary efficacy analysis population (referred to as the Per-Protocol Set for Efficacy) demographics were similar to those in the safety population and included 11’366 participants who received either mNEXSPIKE (SARS-CoV-2 mRNA) (n=5’679) or elasomeran/davesomeran (n=5’687). There were no notable differences in demographics between participants who received mNEXSPIKE and those who received elasomeran/davesomeran.

The population for the relative vaccine efficacy analysis included participants 12 years of age and older who were enrolled from 28 March 2023, and followed for the development of COVID-19 through 31 January 2024. The median length of follow-up was 8 months.
The primary efficacy objective in this study was to demonstrate the non-inferior vaccine efficacy against COVID-19 starting 14 days after vaccination compared to that of elasomeran/davesomeran. The statistical criterion to demonstrate non-inferiority required that the lower bound of the 99.4% CI be >-10% for relative vaccine efficacy. This pre-specified primary objective was successfully met (see Table 2). During this period, the effectiveness of elasomeran/davesomeran against COVID-19 medical encounters and hospitalisations was seen in observational studies.

Table 2. Relative vaccine efficacy against COVID-19* in participants 12 years of age and older starting 14 days after a single dose of mNEXSPIKE or elasomeran/davesomeran – Per-Protocol Set for efficacy

Age	mNEXSPIKE[a]			elasomeran/davesomeran [b]			% Relative vaccine efficacy (99.4% CI)[c]
	Participants (N)	COVID-19 cases (n)	Incidence rate of COVID-19 per 100 person-months	Participants (N)	COVID-19 cases (n)	Incidence rate of COVID-19 per 100 person-months	
All participants	5'679	560	1.4	5'687	617	1.5	9.3 (-6.6, 22.8)

* 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 or diarrhoea.

[a] Dosing was a single dose (10 µg SARS-CoV-2 mRNA).

[b] Dosing was a single dose (50 µg mRNA).

[c] Relative Vaccine Efficacy (rVE) = 1-hazard ratio (mNEXSPIKE vs. elasomeran/davesomeran). Hazard ratio and CI are estimated using a stratified Cox proportional hazard model (stratified by age group per randomisation) with Efron's method of tie handling and with the treatment group as a fixed effect. Alpha-adjusted 2-sided (99.4%) CI for Centers for Dieseas Control and Prevention (CDC)-defined COVID-19 is calculated using Lan-DeMets O'Brien Fleming approximation spending function (nominal one-sided alpha = 0.0028).

The primary immunogenicity analysis population included 621 participants who received mNEXSPIKE and 568 participants who received elasomeran/davesomeran. The baseline characteristics were similar to the safety population/ Per-Protocol Set for Efficacy, as described further above.

A comparison of neutralising antibody concentrations against a pseudovirus expressing SARS-CoV-2 Spike proteins from the original and Omicron BA.4/BA.5 strains was conducted. In the primary immunogenicity analyses of the geometric mean concentration (GMC) ratio following mNEXSPIKE compared to after elasomeran/davesomeran, mNEXSPIKE met the pre-specified non-inferiority criterion of the lower bound of the 95% CI >0.667. Analyses of the difference in seroresponse rates (SSR) also met the pre-specified non-inferiority criterion with the lower bound of the 95% CI of the SRR-difference >-10%. These analyses are summarised in Table 3.

Table 3. Comparison of GMC and SRR 28 days after a single dose of mNEXSPIKE versus 28 days after a single dose of elasomeran/davesomeran – Per-Protocol immunogenicity subset*

Assay	mNEXSPIKE[a] GMC N=621 (95% CI)[b]	elasomeran/ davesomeran[c] GMC N=568 (95% CI)[b]	GMC ratio (mNEXSPIKE / elasomeran/davesomeran) (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)
Original SARS-CoV-2 (D614G)	10'631.9 (9960.2, 11348.9)	8576.5 (8012.5, 9180.1)	1.2 (1.1, 1.4)
	mNEXSPIKE[a] seroresponse[c] N=621 % (95% CI)[e]	**elasomeran/davesomeran seroresponse[d] N=568 % (95% CI)[e]**	**Difference in SRR (mNEXSPIKE – elasomeran/davesomeran) % (95% CI)[f]**
Omicron BA.4/BA.5	79.9 (76.5, 83.0)	65.5 (61.4, 69.4)	14.4 (9.3, 19.4)
Original SARS-CoV-2 (D614G)	83.6 (80.4, 86.4)	72.9 (69.0, 76.5)	10.7 (6.0, 15.4)

N=Number of participants with non-missing data at the corresponding timepoint(s).
* Per-Protocol Immunogenicity Subset included a randomly selected subset of subjects 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] Dosing was a single dose (10 µg of SARS-CoV-2 mRNA).
[b] The log-transformed antibody levels are analysed using an analysis of covariance (ANCOVA) model with the group variable (mNEXSPIKE vs. elasomeran/davesomeran) as fixed effect, adjusted by SARS-CoV-2 status at baseline, randomisation age group, number of prior COVID-19 boosters (0, 1, 2, ≥3), and type of last prior COVID-19 vaccine. Coefficients for Least Square (LS) 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] Elasomeran/davesomeran dosing was a single dose (50 micrograms mRNA).
[d] 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.
[e] 95% CI is calculated using the Clopper-Pearson method.
[f] 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.
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.

Study P301-Japan (Study 2)

Study P301-Japan was a Phase 3 randomised, observer-blind, active-controlled clinical trial that evaluated the immunogenicity and safety of mNEXSPIKE in participants 12 years of age and older in Japan. Randomisation was stratified by age: 12 to 17 years, 18 to 64 years, and 65 years of age and older. The study allowed for the inclusion of participants with stable pre-existing medical conditions, defined as disease not requiring significant change in therapy or hospitalisation for worsening disease during the two months before enrolment, as well as participants with stable human immunodeficiency virus (HIV) infection. A total of 692 participants were randomised in a 1:1 ratio to receive mNEXSPIKE (10 µg SARS-CoV-2 mRNA; n=344), or andusomeran [targeting Omicron XBB.1.5 strain (50 µgmRNA; n=348)]. All participants had previously received at least one dose of a COVID-19 vaccine prior to the study with a median time of 16.7 months since the last dose.

The primary immunogenicity analysis population included 334 participants who received mNEXSPIKE and 334 participants who received andusomeran. Among participants assessed for immunogenicity,

65.0% were male, 35.0% were female, and all participants were Asian. The median age of participants was 52 years (range: 12 to 83 years) and 20.7% of participants were 65 years of age and older.

A comparison of neutralising antibody concentrations against a pseudovirus expressing Omicron XBB.1.5 was conducted. In the primary immunogenicity analyses of the GMC ratio following mNEXSPIKE compared to after andusomeran, mNEXSPIKE met the pre-specified non-inferiority criterion of the lower bound of the 95% CI >0.667. Analyses of the difference in seroresponse rates are summarized (Table 4).

Table 4. Comparison of GMC and SRR 28 days after a single dose of mNEXSPIKE versus 28 days after a single dose of andusomeran – Per-Protocol immunogenicity set*

Assay	mNEXSPIKE[a] GMC (95% CI)[b] N=334	andusomeran[c] GMC (95% CI)[b] N=334	GMC ratio (mNEXSPIKE/ andusomeran) (95% CI)[b]
Omicron XBB.1.5	1757.2 (1580.1, 1954.3)	1470.4 (1322.4, 1635.0)	1.20 (1.03, 1.39)
	mNEXSPIKE[a] seroresponse[d] % (95% CI)[e] N=334	**andusomeran[c] seroresponse[d] % (95% CI)[e] N=334**	**Difference in SRR (mNEXSPIKE-andusomeran) % (95% CI)[f]**
	92.2 (88.8, 94.9)	86.8 (82.7, 90.3)	5.4 (0.8, 10.2)

N=Number of participants with non-missing data at baseline and the corresponding timepoint(s).
* Per-Protocol immunogenicity set included subjects who received study vaccine, 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] mNEXSPIKE dosing was a single dose (10 micrograms of SARS-CoV-2 mRNA).
[b] The log-transformed antibody levels are analysed using an analysis of covariance (ANCOVA) model with the group variable (mNEXSPIKE vs. andusomeran) as fixed effect, adjusted by SARS-CoV-2 status at baseline, randomisation age group, number of prior boosters (0, 1, 2, ≥3), and type of last prior COVID-19 vaccine. LS means are based on observed margin. The resulted LS means, difference of LS means, and 95% CI are back transformed to the original scale for presentation.
[c] single dose.
[d] 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.
[e] 95% CI is calculated using the Clopper-Pearson method.
[f] 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.
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.

Pharmacokinetics

Absorption

Not applicable.

Distribution

Not applicable.

Metabolism

Not applicable.

Elimination

Not applicable.

Kinetics in specific patient groups

Renal impairment

No clinical studies have been conducted to investigate the effect of renal impairment.

Hepatic impairment

No clinical studies have been conducted to investigate the effect of hepatic impairment.

Preclinical data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenicity and reproductive toxicity.

Genotoxicity/Carcinogenicity

Carcinogenicity studies were not performed. The components of the vaccine (lipids and mRNA) are not expected to have genotoxic potential.

Developmental and reproductive toxicity

Animal studies conducted with mNEXSPIKE are insufficient to assess functional effects on male reproductive toxicity.

Reproductive and developmental studies in rats with mNEXSPIKE vaccine did not reveal vaccine-related effects on female fertility, pregnancy, or embryo-foetal or offspring development.

Other information

Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

Shelf life

Do not use this medicine after the expiry date (“EXP”) stated on the pack.

Special precautions for storage

Store in a freezer at -40ºC to -15ºC.
Once thawed, store in a refrigerator (2 °C to 8 °C) and do not refreeze.
Keep the pre-filled syringes in the original carton in order to protect from light.
Keep out of the reach of children.

Storage conditions after thawing

Within the shelf life of 1 year, the vaccine is stable for 30 days when stored at 2 °C to 8 °C and protected from light. At the end of 30 days, the vaccine should be used immediately or discarded (see section “Special precautions for storage”).

Once thawed, the vaccine should not be refrozen.

Upon moving the vaccine to 2 °C to 8 °C storage, the outer carton should be marked with the new expiry date at 2 °C to 8 °C.

If the vaccine is received at 2 °C to 8 °C, it should then be stored at 2 °C to 8 °C. The use by date corresponding to these storage conditions would be marked on a label on the carton. Please note in that case the expiration date (“EXP”) printed on the outer carton and on the pre-filled syringe for storage between -40°C to -15°C is not pasted over.

Pre-filled syringes may be stored at 8 °C to 25 °C for up to 24 hours after removal from refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Do not refrigerate after being stored at 8 °C to 25 °C. Discard the syringe if not used within this time.

Transportation of pre-filled syringe in liquid state at 2°C to 8°C

If transport at -40°C to -15°C is not feasible, available data support transportation of one or more thawed pre-filled syringes in liquid state at 2°C to 8°C (within the 30 day shelf life).
Once thawed and transported in liquid state at 2°C to 8°C, pre-filled syringes should not be refrozen and should be stored at 2°C to 8°C until use.

Instructions for handling
The vaccine should be administered by a trained healthcare professional using aseptic techniques to ensure sterility of the dispersion.

Handling instructions before use

The vaccine is ready to use once thawed.

Do not dilute the product.

Do not shake the pre-filled syringe before use.

The pre-filled syringe is for single-use only.

Do not use if the pre-filled syringe has been dropped or damaged or the security seal on the carton has been broken.

One (1) dose of 0.2 mL can be administered from each pre-filled syringe.

mNEXSPIKE is shipped and supplied either as a frozen or thawed pre-filled syringe (see section “Special precautions for storage”). If the vaccine is frozen, it must be completely thawed before use. Thaw each pre-filled syringe before use, either in the refrigerator or at room temperature, following the instructions in Table 5.

Prior to immediate use, single syringes may be removed from a carton of 1or 10 pre-filled syringes and thawed either in the refrigerator or at room temperature. The remaining syringes must continue to be stored in their original carton in the freezer or refrigerator.

If the vaccine has been thawed at room temperature (15°C to 25°C), the pre-filled syringe is ready to administer. Syringes should not be returned to the refrigerator after being thawed at room temperature.
The pre-filled syringes may be stored at 8°C to 25°C for a total of 24 hours after removal from refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Discard the syringe if not used within this time.

Thaw each pre-filled syringe before use following the instructions below. Pre-filled syringes may be thawed outside the carton or in the carton itself, either in the refrigerator or at room temperature (Table 5).

Table 5. Thawing instructions for mNEXSPIKE pre-filled syringes and cartons before use

Configuration	Thaw instructions and duration			
	Thaw temperature (in a refrigerator) (°C)	Thaw duration (minutes)	Thaw temperature (at room temperature) (°C)	Thaw duration (minutes)
1 pre-filled syringe (removed from carton) or a carton of 1 pre-filled syringes	2 – 8	100	15 – 25	40
10 pre-filled syringes in carton	2 – 8	160	15 – 25	80

Administration
- Do not shake
- Pre-filled syringe should be inspected visually for particulate matter and discolouration prior to administration.
- Do not administer if vaccine is discoloured or containsparticulate matter or has not yet completely defrosted.
- Needles are not included in the pre-filled syringe cartons.
- Use a sterile needle of the appropriate size for intramuscular injection (21-gauge or thinner needles).
- With tip cap upright, remove tip cap by twisting counter-clockwise 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.
- Uncap the needle when ready for administration.
- The vaccine should be administered immediately after uncapping.
- Administer the entire dose intramuscularly.
- Discard the pre-filled syringe after single use.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Authorisation number

70272 (Swissmedic) mNEXSPIKE dispersion for injection in pre-filled syringe

Packs

Pack-sizes:

1 pre-filled syringe per carton. The pre-filled syringe contains one dose of 0.2 mL [B].

10 pre-filled syringes per carton. Each pre-filled syringe contains one dose of 0.2 mL [B].

mNEXSPIKE is supplied in a pre-filled syringe (polymeric barrel) with plunger stopper and a rubber tip cap (without needle).

Marketing authorisation holder

Moderna Switzerland GmbH, Basel

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