COVID-19 Vaccine Explainer

7 FEBRUARY 2021[1]

World Health Organization

Moderna COVID-19 vaccine (mRNA-1273)

Manufacturer: ModernaTX, Inc.

The Moderna COVID-19 vaccine is a messenger RNA (mRNA) based vaccine against coronavirus disease 2019 (COVID-19). The host cells receive the instruction from the mRNA to produce protein of the S-antigen unique to SARS-CoV-2, allowing the body to generate an immune response and to retain that information in memory immune cells. Efficacy shown in clinical trials in participants who received the full series of vaccine (2 doses) and had negative baseline SARS-CoV-2 status, was approximately 94% based on a median follow-up of 9 weeks. The data reviewed at this time support the conclusion that the known and potential benefits of mRNA-1273 vaccine outweigh the known and potential risks.

Date of WHO Emergency Use Listing (EUL) recommendation: decision date anticipated for the end of February 2021

Date of prequalification (PQ): currently no information
National regulatory authorities (NRAs) can use reliance approaches for in-country authorization of vaccines based on WHO PQ/EUL or emergency use authorizations by stringent regulatory authorities (SRAs).

Product characteristics

Presentation	Frozen, sterile, preservative-free, multi-dose suspension
Number of doses	One vial contains 10 doses of vaccine after thawing
Vaccine syringe type and needle size	Auto-disable (AD) syringe: 0.5 mL Needle for intramuscular injection 23G × 1” (0.60 × 25 mm)

Schedule and administration

Recommended for age	18 years of age and above Vaccination is recommended for older persons without an upper age limit.
Recommended schedule	2 doses (100 µg, 0.5 mL each) at a recommended interval of 28 days: Dose 1: at the start date Dose 2: 28 days after first dose. If the second dose is inadvertently administered earlier than 28 days after the first, the dose does not need to be repeated. If the second dose is inadvertently delayed, it should be given as soon as possible thereafter according to manufacturer’s instructions. If a delay is judged necessary, WHO currently recommends that the interval between doses may be extended up to 42 days. Both doses are necessary for protection. The same product should be used for both doses.

[1]Contents will be updated as new information becomes available.

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Schedule and administration contd.

Route and site of administration	Intramuscular (i.m.) administration The preferred site is deltoid muscle.
Dosage	0.5 mL (single dose)
Diluent	None needed
Mixing syringe	None needed
Preparation/ reconstitution/ dilution requirement	**No dilution is required.** **Thaw each vial before use:** • Thaw vaccine at room temperature at 15 to 25 °C for 1 hour. OR • Thaw vaccine in refrigerator at +2 to +8 °C for 2 hours and 30 minutes. Let vial sit at room temperature for 15 minutes before vaccine administration. **Vaccine administration:** 1. Once thawed, vaccine is ready to use, do not dilute. 2. Swirl the vial gently, do not shake. 3. Inspect the vial to make sure that the liquid is white to off-white in colour. The vaccine may contain white or translucent product-related particles. Do not use if any other particles or discoloration are present, discard the vial. 4. Record date and time of the first use (first puncture and withdrawal of the dose) on the vial label. 5. Before each vaccine withdrawal, swirl the vial gently again and do not shake. 6. Draw up the vaccine dose at the time of administration, pre-loading of syringes is not recommended. 7. Use all vaccine within 6 hours after first puncture. Discard vial when there is not enough vaccine to obtain a complete dose of 0.5 mL. Do not combine residual vaccine from multiple vials.
Multi-dose vial policy	After the first dose has been withdrawn, keep between 2 °C and 25 °C and discard any unused vaccine after 6 hours, or at the end of the immunization session, whichever comes first.
Contraindications	• Known history of anaphylaxis to any component of the vaccine. In particular, mRNA-1273 should not be administered to individuals with a known history of anaphylaxis to polyethylene glycol (PEG). • Persons who developed anaphylaxis after the first dose should not receive a second dose of mRNA-1273 vaccine or of any other mRNA COVID-19 vaccine (e.g. COMIRNATY® Pfizer-BioNTech).
Precautions	• For persons with known history of anaphylaxis to any other vaccine or injectable therapy, a risk assessment should be conducted by the relevant specialist. Such persons may still receive vaccination but they should be counseled about the potential risks of anaphylaxis; risks should be weighed against benefits of vaccination. • All persons should be vaccinated in health-care settings where anaphylaxis can be immediately treated and observed 15 minutes after vaccination and persons with previous history of anaphylaxis should be observed for 30 minutes after vaccination. • Food, contact or seasonal allergies, including to eggs, gelatin and latex, are not considered precautions or contraindications. • Vaccination of people suffering from acute severe febrile illness (body temperature over 38.5 °C) should be postponed until they are afebrile. • Vaccination of persons with acute COVID-19 should be postponed until they have recovered from acute illness and criteria for discontinuation of isolation have been met.

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Schedule and administration contd.

Special population groups (based on available data as of January 2021)	• For persons with **comorbidities** such as chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease and human immunodeficiency virus (HIV) infection, that have been identified as increasing the risk of severe COVID-19, vaccination is recommended. • For extremely frail older persons and persons above 95 years of age with life expectancy anticipated to be less than 3 months, an individual risk-benefit assessment will need to be conducted. • Available data on administration in **pregnant women** are insufficient to inform vaccine-associated risks in pregnancy. Vaccination is not currently recommended during pregnancy unless the benefit of vaccinating (e.g. health workers at high risk of exposure and pregnant women with comorbidities) outweighs the potential vaccine risks. WHO does not recommend pregnancy testing prior to vaccination or delaying pregnancy following vaccination. • There are no data on the safety of mRNA COVID-19 vaccines for **lactating women** or on the effects on **breastfed children**. As this is not a live virus vaccine, and the mRNA does not enter the nucleus of the cell and is degraded quickly, it is therefore biologically and clinically unlikely to pose a risk to the breastfeeding child. A lactating woman who is a part of a group recommended for vaccination should be offered vaccination. WHO does not recommend discontinuing breastfeeding after vaccination. • **Immunocompromised persons** may have diminished immune response to vaccine. Nevertheless, if part of a recommended group for vaccination, they may be vaccinated. [Information and, where possible, counselling about vaccine safety and efficacy profiles in immunocompromised persons should be provided to inform individual benefit–risk assessment.] • Persons with **autoimmune conditions** who have no contraindications to vaccination may be vaccinated. • **HIV-positive persons** who are well controlled on highly active antiretroviral therapy and are part of a group recommended for vaccination can be vaccinated. Available data for HIV-positive persons who are not well controlled on therapy are currently insufficient to allow assessment of vaccine efficacy and safety in this group. Testing for HIV infection prior to vaccine administration is not necessary. • Persons with a history of Bell's palsy may receive mRNA-1272 vaccine if no contraindications. Currently there is no conclusive evidence that observed cases were causally related to vaccination. • For persons who have received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, vaccination should be deferred for at least 90 days to avoid interference of treatment with vaccine-induced immune response.

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Stability and storage

Vaccine storage temperature	Store in the original carton in a freezer at -25 to -15 °C. **Do not store on dry ice or below -40 °C.**
Shelf life at different temperatures	Frozen suspension in **an unopened vial at storage temperature** between -25 and -15 °C: until expiration date. Confirm expiration date by looking up the lot number printed on the carton and vial, enter it here: https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup and press submit. **Frozen unopened** vaccine vial in freezer at -25 and -15 °C: from receipt until expiration date **Thawed unopened** vaccine vial in refrigerator at +2 to +8 °C: up to 30 days **Thawed unopened** vaccine vial in cool storage up to room temperature from +8 °C up to +25 °C: up to 12 hours **Thawed punctured vial** at +2 to +25 °C: 6 hours after the first dose has been withdrawn. Do not refreeze after thawing.
Freeze sensitivity	**Never** refreeze thawed vials. Do not store in insulated passive container with dry ice or ultra-low temperature phase-change material (PCM), or in freezer below -40 °C.
Light sensitivity	Store in the original carton to protect from light. Avoid exposure to direct sunlight and ultraviolet light.
Conditions before use	When thawed at +2 to +8 °C, keep at room temperature (up to +25 °C) for 15 minutes before use. When thawed at room temperature (up to +25 °C) for 1 hour, vaccine can be used immediately.
Wastage rates	Will be dependent on country context.
Buffer stock needed	Will be dependent on country context.

Labelling and packaging

Vaccine Vial Monitor (VVM) (if yes, where located and type)	Initial pandemic supply will not include a VVM.
Labelling information on vial label (QR code, datamatrix, barcode) and type of information embedded on them	Not finalized
Labelling information on secondary packaging (QR code, datamatrix, barcode) and type of information embedded on them	Not finalized
Labelling information on tertiary packaging (QR code, datamatrix, barcode) and type of information embedded on them	Not finalized
Secondary packaging dimension and volume	Box holding 10 vials/100 doses: 13.97 × 5.59 × 6.35 cm Volume per dose: 4.96 cm^3/dose
Tertiary packaging dimension and volume	Carton containing 12 secondary boxes with a total of 120 vials (1200 doses) External dimensions 26.7 × 16.9 × 15.5 cm

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Safety information*

Possible events (by frequency)	• Observed events frequent, mostly mild to moderate and short lived • Less frequent and severe in older (≥65 years) than in younger adults (18–64 years) • Generally more frequent after the second dose compared to the first across all age groups **Very common (≥1/10)** Headache, nausea, vomiting, myalgia, arthralgia and stiffness, pain at the injection site, fatigue, chills, fever, lymphadenopathy **Common (≥1/100 to <1/10):** Rash, injection site redness or swelling, vomiting, diarrhoea **Uncommon (≥1/1 000 to <1/100):** Itchiness at the injection site **Rare (≥1/10 000 to < 1/1 000):** Facial swelling, Bell's palsy (acute peripheral facial paralysis) **Not known (cannot be estimated from available data):** Anaphylaxis, hypersensitivity
Co-administration of vaccines/medicines	There should be a minimum interval of 14 days between administration of this and any other vaccine against other diseases, until data on co-administration become available.

*From clinical studies

Important reminders

Vaccination session and vaccine administration:

Before, during, and after vaccination, all people should continue to follow current guidance for protection from COVID-19 in their area (e.g. wearing a mask, keeping physical distance, hand hygiene).

A person presenting with COVID-19 symptoms should not be vaccinated. Vaccination may be offered to people who have recovered from COVID-19, whether symptomatic or asymptomatic.

Testing is not recommended for the purpose of decision-making about vaccination, however, based on current data, persons with PCR-confirmed SARS-CoV-2 infection in the preceding 6 months may choose to delay vaccination until near the end of this period

This vaccine should only be administered in settings where appropriate medical treatment to manage anaphylaxis is immediately available, that is, settings with (i) the necessary resources and trained health workers, and (ii) that allow for at least 15 minutes of post-vaccination observation. (For more information on AEFI kits and treatment, please refer to the training materials – COVID-19 vaccination training for health workers, Module 4: AEFI monitoring at https://openwho.org/courses/covid-19-vaccination-healthworkers-en).

Before vaccination, advise vaccine recipient about possible post-vaccination symptoms and observe post-vaccination for at least **15 minutes**.

Persons with history of allergic reactions and other conditions listed in the warnings and/or precautions in the package insert should be observed **30 minutes** post vaccination.

To alleviate post-vaccination symptoms, antipyretic or analgesics may be taken (routine prophylaxis to prevent the symptoms is not recommended due to lack of information on impact on immune response).

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Important reminders contd.

Encourage a vaccine recipient to complete the vaccination series to optimize protection and schedule the time for the second dose. The same vaccine product should be used for both doses. When scheduling vaccination for occupational groups (e.g. health workers) consideration should be given to the reactogenicity profile of mRNA-1273 vaccine observed in clinical trials, occasionally leading to time off work in the 24-48 hours following vaccination.

Resources and more information at:

https://www.modernatx.com/covid19vaccine-eua/providers/about-vaccine
https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf
https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-moderna-epar-product-information_en.pdf
https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19