World Health Organization
REGIONAL OFFICE FOR Europe

July 2021

FACT SHEET FOR HEALTH WORKERS

Moderna COVID-19 (mRNA-1273) vaccine

1. GENERAL INFORMATION

- **Vaccine name:** Moderna
- **Age indication:** 18 years of age and older
- **Vaccine platform:** mRNA vaccine
- **Dosage:** 100 µg, 0.5 ml
- **Vaccine characteristics**: Non-live vaccine, mRNA formulated in SM-102 lipid nanoparticles allowing uptake into cell cytosol; mRNA degrades rapidly and does not enter cell nucleus
- **Route & site of administration:** Intramuscular in the deltoid muscle of the upper arm

2. VACCINE SCHEDULE

- Two doses given with an interval of 28 days between doses.
- Countries that have not yet achieved high vaccination coverage rates in the high priority groups and that are experiencing a high incidence of COVID-19 cases combined with vaccine supply constraints may extend the inter-dose interval up to 12 weeks to achieve high first-dose coverage in high-priority groups.
- A series started with Moderna COVID-19 vaccine should be completed with this product.
- Minimum 14 days interval between administering Moderna COVID-19 vaccine and any other vaccine.

3. VACCINE EFFICACY (VE)

- The vaccine was highly efficacious against laboratory-confirmed COVID-19 from 14 days after the second dose until the end of the follow-up period (approximately two months after second dose).
- VE was high in subgroups at higher risk of severe COVID-19, including people ≥65 years of age and those with comorbidities.*

VE IN PARTICIPANTS AFTER HAVING RECEIVED FULL SERIES OF VACCINATION (2 DOSES)	
Overall	
If limited to participants without previous SARS-CoV-2 infection	• 94.1% VE (95% CI: 89.3–96.8%) regardless of sex, race or ethnic group of vaccine recipients (11 cases in vaccinated group, 185 cases in placebo group)
Including participants with/without evidence of prior SARS-CoV-2 infection	• 93.6% VE (95% CI: 88.5–96.4%)
By age groups	
individuals aged 18–64 years	• 95.6% VE (95% CI: 90.6–97.9%)
individuals aged ≥65 years	• 86.4% VE (95% CI: 61.4–95.2%)
individuals aged ≥75 years	• 100% VE (95% CI: NE–100%)
With underlying condition (18–64 years of age):**	• 94.4% VE

CI = confidence interval. NE = not estimable.

** Comorbidities studied include hypertension; diabetes;** chronic lung disease;** severe obesity (body mass index ≥40 kg/m2);** significant cardiovascular disease;** kidney and liver disease;** chronic (stable and con- trolled) HIV;** hepatitis B or C infection.*

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6. SARS-COV-2 VARIANTS

- SARS-CoV-2 viruses undergo evolution. Variants of concern may have higher transmissibility, disease severity, risk of reinfection, or a change in antigenic composition resulting in lower vaccine effectiveness.
- Preliminary data show some reduction in neutralization activity of mRNA-1273 against the Beta (B.1.351) variant, and less marked reduction against the other variants of concern (Gamma (P1) and Alpha (B.1.1.7)).
- The impact of variants of concern on vaccine effectiveness remains unknown to date, especially for the recently emerged Delta (B.1.617.2) variant.

7. VACCINE SAFETY

- The most common solicited adverse reactions included injection site pain, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary swelling/tenderness, fever, and injection site swelling and redness.
- Adverse reactions were mostly mild, moderate and short lived (mean duration: 2.6–3.2 days).
- Adverse reactions were generally milder and less frequent in the older age group (≥65 years) compared to the younger age group (18–64 years).
- Adverse reactions tend to increase after the second dose.
- The reactogenicity and safety profile in people with previous SARS-CoV-2 infection was comparable to subjects seronegative for SARS-CoV-2.
- Very rare cases of myocarditis and pericarditis have been observed following vaccination with the mRNA COVID-19 vaccines. These cases occurred more often in younger men and after the second dose of the vaccine, typically within few days after vaccination. Current evidence suggests a likely causal association between myocarditis and the mRNA vaccines. The risk of myocarditis and pericarditis is very low and the benefits of mRNA COVID-19 vaccines in reducing hospitalizations and deaths due to COVID-19 infections outweigh the risks.
  Clinicians should instruct vaccinated individuals to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as new onset and persisting chest pain, shortness of breath, or palpitations following vaccination. Healthcare providers should report all myocarditis and other adverse events observed with mRNA and other vaccines.

8. CONTRAINDICATIONS AND PRECAUTIONS

Contraindications

- History of anaphylaxis to any component of the vaccine. If anaphylaxis occurs after the first dose, a second dose should not be administered.

Precautions

- A history of anaphylaxis to any other vaccine or injectable therapy or to the first dose of this vaccine (Subject to individual risk–benefit assessment, this vaccine could be provided under close medical supervision)
- Acute febrile illness (body temperature over 38.5 °C)
- Individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following intramuscular administration

9. SPECIAL CONDITIONS AND GROUPS

CONDITION/GROUP	SAGE RECOMMENDATION
Older people	• Vaccination is recommended for older persons without an upper age limit.
Children, adolescents <18 years of age	• Vaccination in individuals <18 years old is not recommended.
Pregnancy	• Vaccination is recommended when the benefit of vaccination to a pregnant woman outweighs the potential risks.
Breastfeeding	• Vaccination is recommended as in other adults. • Discontinuation of breastfeeding after vaccination is not recommended.
Immunocompromised persons	• May be vaccinated if a part of a group recommended for vaccination. • Immune response may be reduced.
Persons living with HIV	• May be vaccinated if a part of a group recommended for vaccination. • Immune response may be reduced.
Persons with current acute COVID-19	• Vaccination should be deferred until the person has recovered and the criteria for discontinuation of isolation are met.

Persons who have previously had SARS-CoV-2 infection	• Vaccination may be offered regardless of a person's history of symp-tomatic or asymptomatic SARS-CoV-2 infection.
Persons who previously received passive antibody therapy as part of a COVID-19 treatment	• Vaccination should be deferred for at least 90 days.

PCR = polymerase chain reaction; SAGE = Strategic Advisory Group of Experts on Immunization.

10 SARS COV-2 TESTS

- Prior receipt of the vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests for diagnosis of acute/current SARS-CoV-2 infection.
- Antibody testing is not currently recommended to assess immunity to COVID-19 following Moderna vaccination.
- To evaluate for evidence of prior infection in an individual who has received Moderna, a test that specifically evaluates IgM or IgG to the nucleocapsid protein should be used.

11 ROLE OF VACCINES AMONG OTHER PREVENTIVE MEASURES

- As there is not yet sufficient evidence of the extent of vaccine impact on transmission, government advice on non-pharmaceutical interventions should continue to be followed by vaccinated individuals, as well as those who have not yet been vaccinated.

12 SOURCES

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WHO/EURO: 2021-2024-41779-59421