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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Revision of Precautions

## Coronavirus modified uridine RNA vaccine (SARS-CoV-2)

### (COVID-19 Vaccine Moderna Intramuscular Injection)

December 3, 2021

#### **Therapeutic category**

Vaccines

#### **Non-proprietary name**

Coronavirus modified uridine RNA vaccine (SARS-CoV-2)

#### **Safety measure**

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Although the causal relationship with this vaccine is unknown, cases of myocarditis and pericarditis have been reported following inoculation with this vaccine.</u> Vaccine recipients or their caregivers should be instructed in advance to seek medical attention immediately if they experience or notice any symptoms that could suggest myocarditis or pericarditis (such as chest pain, palpitation, oedema, dyspnoea, and tachypnoea).</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>(N/A)</p> <p>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p><u>Although the causal relationship is unknown,</u> cases of myocarditis and pericarditis have been reported overseas following inoculation with coronavirus modified uridine RNA vaccine (SARS-CoV-2). Reported cases for the initial immunization have occurred predominantly in male adolescents and young adults and onset was typically within several days after the second vaccination. It</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Myocarditis, pericarditis may occur.</u> Vaccine recipients or their caregivers should be instructed in advance to seek medical attention immediately if they experience or notice any symptoms that could suggest myocarditis or pericarditis (such as chest pain, palpitation, oedema, dyspnoea, and tachypnoea).</p> <p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p><u>Myocarditis, pericarditis</u></p> <p>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p>Cases of myocarditis and pericarditis have been reported overseas following inoculation with coronavirus modified uridine RNA vaccine (SARS-CoV-2). Reported cases for the initial immunization have occurred predominantly in male adolescents and young adults and onset was typically within several days after the second vaccination. It has also been reported that in most cases, patients</p>

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has also been reported that in most cases, patients had improvement of symptoms by resting in a supine position in hospital.

It is suggested that the frequency of myocarditis and pericarditis was higher in the male adolescents and young adults inoculated with this vaccine by comparing the reporting rates of myocarditis and pericarditis in the domestic suspected adverse reaction reports after the start of vaccination and the estimated background incidence rates of myocarditis and pericarditis in the general population utilizing a domestic medical information database.

(N/A)

had improvement of symptoms by resting in a supine position in hospital.

It is suggested that the frequency of myocarditis and pericarditis was higher in the male adolescents and young adults following the second inoculation with this vaccine by comparing the reporting rates of myocarditis and pericarditis in the domestic suspected adverse reaction reports after the start of vaccination and the estimated background incidence rates of myocarditis and pericarditis in the general population utilizing a domestic medical information database.

Although the causal relationship is unknown, cases of localized swelling (particularly in the face) that developed around the areas of filler placements following inoculation with Coronavirus modified uridine RNA vaccine (SARS-CoV-2) have been reported overseas in vaccine recipients with a history of injection of dermatological fillers.

N/A: Not Applicable. No corresponding language is included in the current package insert.

(References) Material for the Side Effect Subcommittee of the Immunization and Vaccine Section Meeting in the Health Science Council (the 73rd meeting), and the 2021 Subcommittee on Drug Safety of the Committee on Drug Safety in the Pharmaceutical Affairs and Food Sanitation Council (the 23rd meeting) (joint meeting)

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