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Translated by
Pharmaceuticals and Medical Devices Agency



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)

July 7, 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.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS (N/A)</p> <p>15. OTHER PRECAUTIONS (N/A)</p>	<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. Vaccinees 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).</u></p> <p>15. OTHER PRECAUTIONS</p> <p><u>15.1 Information Based On Clinical Use</u></p> <p><u>Although the causality is unknown, cases of myocarditis and pericarditis have been reported overseas following inoculation with coronavirus modified uridine RNA vaccine (SARS-CoV-2). Reported cases have occurred predominantly in male adolescents and young adults and onset was typically within several days after second vaccination. It has also been reported that in most cases, patients had improvement of symptoms by resting in a supine position in hospital.</u></p>

<Reference>

Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

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

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