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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)

(Comirnaty intramuscular injection, Comirnaty intramuscular injection for 5 to 11 years old, Spikevax Intramuscular Injection)

June 10, 2022

Therapeutic category

Vaccines

Non-proprietary name

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

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Safety measure

Precautions should be revised.

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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>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Cases of Guillain-Barré syndrome have been reported following inoculation with Coronavirus modified uridine RNA vaccine (SARS-CoV-2). Vaccine recipients or their caregivers should be instructed in advance to seek medical attention immediately if the vaccine recipients experience any symptoms that could suggest Guillain-Barré syndrome (such as flaccid paralysis starting from distal limb, decreased or absent tendon reflex).</u></p>

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

(References) Material for the Side Effect Subcommittee of the Immunization and Vaccine Section Meeting in the Health Science Council (the 80th meeting), and the 2022 Subcommittee on Drug Safety of the Committee on Drug Safety in the Pharmaceutical Affairs and Food Sanitation Council (the 5th meeting) (joint meeting) (Only in Japanese)

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