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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty RTU intramuscular injection (Bivalent: Original/Omicron BA.1), Comirnaty RTU intramuscular injection (Bivalent: Original/Omicron BA.4-5), Spikevax Intramuscular Injection (Bivalent: Original/Omicron BA.1))

October 19, 2022

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 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
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION Timing of vaccination The booster dose may be administered at least 5 months after receiving the previous SARS-CoV-2 vaccine.	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION Timing of vaccination The booster dose may be administered at least 3 months after receiving the previous SARS-CoV-2 vaccine.

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