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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

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

(Comirnaty intramuscular injection)

April 25, 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 Booster dose Timing of vaccination The third dose may be administered as a booster dose at least 6 months after the second dose. No clinical studies have been conducted on the booster dose of this vaccine in people who have received the primary series of other SARS-CoV-2 vaccines.	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION Booster dose Timing of vaccination The third dose may be administered as a booster dose at least 5 months after the second dose. For the fourth dose, the vaccination may be considered in elderly people, etc. based on the benefit/risk balance at least 5 months after the third dose. The effectiveness and safety on the booster dose of this vaccine in people who have received other SARS-CoV-2 vaccines have not been established.

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

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