Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Coronavirus modified uridine RNA vaccine (SARS-CoV-2) (Comirnaty intramuscular injection (Monovalent: Original))

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

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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 Individuals who receive vaccinations Individuals 12 years of age and older. The necessity of a booster dose should be judged based on the benefit/risk balance, the prevalence status of SARS-CoV-2, and the characteristics of each person. 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.	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION Booster dose Individuals who receive vaccinations Individuals 12 years of age and older who have previously received SARS-CoV-2 vaccines as primary series or a booster dose/doses. The necessity of a booster dose should be judged based on the benefit/risk balance, the prevalence status of SARS-CoV-2, and the characteristics of each person. Timing of vaccination The booster dose may be administered at least 3 months after receiving the previous SARS-CoV-2 vaccine. (deleted) The effectiveness and safety on the booster dose of this vaccine in people who have received SARS-CoV-2 vaccines other than this vaccine have not been established.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp