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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)

March 23, 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
<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p>Booster dose</p> <p>Individuals who receive vaccinations</p> <p>Individuals <u>18 years of age and older</u>. 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.</p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p>Booster dose</p> <p>Individuals who receive vaccinations</p> <p>Individuals <u>12 years of age and older</u>. 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.</p>

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