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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)

September 21, 2021

Therapeutic category

Vaccines

Non-proprietary name

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

Pharmaceuticals and Medical Devices Agency

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Safety measure

Precautions should be revised in the package insert.

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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 data-bbox="237 308 1133 336">7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p data-bbox="266 405 483 434">Number of doses</p> <p data-bbox="266 453 1133 481">This vaccine has had its effectiveness confirmed as a two-dose series.</p> <p data-bbox="266 501 1133 625">Completion of both doses of the series with this vaccine should be ensured and no other vaccines with the same indications should be used in this vaccination series.</p>	<p data-bbox="1155 308 2029 336">7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p data-bbox="1184 405 1402 434">Number of doses</p> <p data-bbox="1184 453 2051 481">This vaccine has had its effectiveness confirmed as a two-dose series.</p> <p data-bbox="1184 501 2051 625"><u>In principle,</u> completion of both doses of the series with this vaccine should be ensured and no other vaccines with the same indications should be used in this vaccination series.</p>

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