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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)

(Spikevax 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.

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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>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p>Booster dose</p> <p>Timing of vaccination</p> <p>The third dose may be administered as a booster dose at least <u>6 months</u> after the second dose.</p> <p><u>No clinical studies have been conducted</u> on the booster dose (0.25 mL) of this vaccine in people who have received <u>the primary series of other SARS-CoV-2 vaccines.</u></p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p>Booster dose</p> <p>Timing of vaccination</p> <p>The third dose may be administered as a booster dose at least <u>5 months</u> after the second dose.</p> <p><u>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.</u></p> <p><u>The effectiveness and safety</u> on the booster dose (0.25 mL) of this vaccine in people who have received other SARS-CoV-2 vaccines <u>have not been established.</u></p>

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

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