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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 (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.

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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>Individuals who receive vaccinations</p> <p>Individuals 18 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.</p> <p>Timing of vaccination</p> <p>The <u>third</u> dose may be administered <u>as a booster dose</u> at least <u>5</u> months after <u>the second dose</u>.</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>The effectiveness and safety on the booster dose of this vaccine in people who have received <u>other</u> SARS-CoV-2 vaccines have not been established.</p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p>Booster dose</p> <p>Individuals who receive vaccinations</p> <p>Individuals 18 years of age and older <u>who have previously received SARS-CoV-2 vaccines as primary series or a booster dose/doses.</u></p> <p>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>Timing of vaccination</p> <p>The <u>booster</u> dose may be administered at least <u>3</u> months after <u>receiving the previous SARS-CoV-2 vaccine.</u></p> <p>(deleted)</p> <p>The effectiveness and safety on the booster dose of this vaccine in people who have received SARS-CoV-2 vaccines <u>other than this vaccine</u> have not been established.</p>

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