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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

Recombinant COVID-19 (SARS-CoV-2) vaccine

(Nuvaxovid Intramuscular Injection)

July 8, 2022

Therapeutic category

Vaccines

Non-proprietary name

Recombinant COVID-19 (SARS-CoV-2) vaccine

Safety measure

Precautions should be revised.

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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>8. IMPORTANT PRECAUTIONS</p> <p>(N/A)</p>	<p>8. IMPORTANT PRECAUTIONS</p> <p><u>Cases of myocarditis, pericarditis have been reported. Vaccine recipients or their caregivers should be instructed in advance to seek medical attention immediately if they experience or notice any symptoms that could suggest myocarditis or pericarditis (such as chest pain, palpitation, oedema, dyspnoea, and tachypnoea).</u></p>

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

(References) Material for the Side Effect Subcommittee of the Immunization and Vaccine Section Meeting in the Health Science Council (the 81st meeting), and the 2022 Subcommittee on Drug Safety of the Committee on Drug Safety in the Pharmaceutical Affairs and Food Sanitation Council (the 6th meeting) (joint meeting) (Only in Japanese)

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