

Published by
Ministry of Health, Labour and Welfare



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

COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector)

October 12, 2023

Therapeutic category

Vaccines

Non-proprietary name

COVID-19 (SARS-CoV-2) vaccine (recombinant chimpanzee adenovirus vector)

Safety measure

PRECAUTIONS should be revised.

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
<p>8. IMPORTANT PRECAUTIONS (N/A)</p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Persons to Be Vaccinated with Caution (Persons in whom the decision to vaccinate must be made with caution) (N/A)</p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions (N/A)</p>	<p>8. IMPORTANT PRECAUTIONS <u>Since immune thrombocytopenia has been reported following inoculation with this vaccine, a platelet count test should be performed as necessary.</u></p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Persons to Be Vaccinated with Caution (Persons in whom the decision to vaccinate must be made with caution) <u>Persons with a history of immune thrombocytopenia</u> <u>The platelet count should preferably be monitored.</u></p> <p>11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions <u>Immune thrombocytopenia</u></p>

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

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