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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

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

September 21, 2021

Therapeutic category

Vaccines

Non-proprietary name

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

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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 1133 576">This vaccine has had its effectiveness confirmed as a two-dose series. 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 2040 336">7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p data-bbox="1184 405 2040 576">This vaccine has had its effectiveness confirmed as a two-dose series. <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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