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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

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

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> 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
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION
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	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
used in this vaccination series.	should be used in this vaccination series.

Pharmaceuticals and Medical Devices Agency

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