

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

## Coronavirus modified uridine RNA vaccine (SARS-CoV-2)

### (COVID-19 Vaccine Moderna Intramuscular Injection)

September 21, 2021

#### **Therapeutic category**

Vaccines

#### **Non-proprietary name**

Coronavirus modified uridine RNA vaccine (SARS-CoV-2)

#### **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: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

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 1111 336">7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p data-bbox="266 405 483 434">Number of doses</p> <p data-bbox="266 453 1133 481">This vaccine has had its effectiveness confirmed as a two-dose series.</p> <p data-bbox="266 501 1133 625">Completion of both doses of the series with this vaccine should be ensured and no other SARS-CoV-2 vaccines should be used in this vaccination series.</p>	<p data-bbox="1155 308 2029 336">7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p data-bbox="1184 405 1402 434">Number of doses</p> <p data-bbox="1184 453 2051 481">This vaccine has had its effectiveness confirmed as a two-dose series.</p> <p data-bbox="1184 501 2051 625"><u>In principle,</u> completion of both doses of the series with this vaccine should be ensured and no other SARS-CoV-2 vaccines should be used in this vaccination series.</p>

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)