

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)

October 15, 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

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>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p>(N/A)</p>	<p>15. OTHER PRECAUTIONS</p> <p>15.1 Information Based on Clinical Use</p> <p><u>It is suggested that the frequency of myocarditis and pericarditis was higher in the male adolescents and young adults inoculated with this vaccine by comparing the reporting rates of myocarditis and pericarditis in the domestic suspected adverse reaction reports after the start of vaccination and the estimated background incidence rates of myocarditis and pericarditis in the general population utilizing a domestic medical information database.</u></p>

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

(References) Material for the Side Effect Subcommittee of the Immunization and Vaccine Section Meeting in the Health Science Council (the 70th meeting), and the 2021 Subcommittee on Drug Safety of the Committee on Drug Safety in the Pharmaceutical Affairs and Food Sanitation Council (the 19th meeting) (joint meeting)

Pharmaceuticals and Medical Devices Agency

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