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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

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

(Comirnaty intramuscular injection)

December 3, 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.

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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
8. IMPORTANT PRECAUTIONS Shock, anaphylaxis may occur. Vaccine recipients should be carefully questioned regarding their history of hypersensitivity prior to, and preferably be monitored for their conditions for a certain amount of time following, inoculation with this vaccine.	8. IMPORTANT PRECAUTIONS Shock, anaphylaxis may occur. Vaccine recipients should be carefully questioned regarding their history of hypersensitivity prior to, and preferably be monitored for their conditions for a certain amount of time following, inoculation with this vaccine. In addition, individuals who have developed shock, anaphylaxis following inoculation with this vaccine should not be inoculated with this vaccine thereafter.
Although the causal relationship with this vaccine is unknown, cases of myocarditis and pericarditis have been reported following inoculation with this vaccine. Vaccine recipients or their caregivers should be instructed in advance to seek medical attention immediately if they experience or notice any symptoms that could suggest myocarditis or pericarditis (such as chest pain, palpitation, oedema, dyspnoea, and tachypnoea).	Myocarditis, pericarditis may occur. Vaccine recipients or their caregivers should be instructed in advance to seek medical attention immediately if they experience or notice any symptoms that could suggest myocarditis or pericarditis (such as chest pain, palpitation, oedema, dyspnoea, and tachypnoea).
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Shock, anaphylaxis Individuals who have developed shock, anaphylaxis following	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Shock, anaphylaxis (Deleted)

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inoculation with this vaccine should not be inoculated with this vaccine thereafter. (N/A) 11.2 Other Adverse Reactions <table><tr><td>Site</td><td>Adverse reactions</td></tr><tr><td>Immune system</td><td>Hypersensitivity (rash, pruritus, erythema, urticarial, angioedema, etc.)</td></tr></table> 15. OTHER PRECAUTIONS 15.1 Information Based on Clinical Use Although the causal relationship is unknown, cases of myocarditis and pericarditis have been reported overseas following inoculation with coronavirus modified uridine RNA vaccine (SARS-CoV-2). Reported cases for the initial immunization have occurred predominantly in male adolescents and young adults and onset was typically within several days after the second vaccination. It has also been reported that in most cases, patients had improvement of symptoms by resting in a supine position in hospital. It is suggested that the frequency of myocarditis and pericarditis was higher in the male adolescents and young adults inoculated	Myocarditis, pericarditis 11.2 Other Adverse Reactions <table><tr><td>Site</td><td>Adverse reactions</td></tr><tr><td>Immune system</td><td>Hypersensitivity (rash, pruritus, erythema, urticarial, angioedema, facial swelling, etc.)</td></tr></table> 15. OTHER PRECAUTIONS 15.1 Information Based on Clinical Use Cases of myocarditis and pericarditis have been reported overseas following inoculation with coronavirus modified uridine RNA vaccine (SARS-CoV-2). Reported cases for the initial immunization have occurred predominantly in male adolescents and young adults and onset was typically within several days after the second vaccination. It has also been reported that in most cases, patients had improvement of symptoms by resting in a supine position in hospital. It is suggested that the frequency of myocarditis and pericarditis was higher in the male adolescents and young adults following the

with the other coronavirus modified uridine RNA vaccine (SARS-CoV-2) 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. (N/A)	second inoculation with this vaccine for the initial immunization 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. Although the causal relationship is unknown, cases of localized swelling (particularly in the face) that developed around the areas of filler placements following inoculation with Coronavirus modified uridine RNA vaccine (SARS-CoV-2) have been reported overseas in vaccine recipients with a history of injection of dermatological fillers.

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 73rd meeting), and the 2021 Subcommittee on Drug Safety of the Committee on Drug Safety in the Pharmaceutical Affairs and Food Sanitation Council (the 23rd meeting) (joint meeting)