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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

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

July 27, 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 Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
2. PERSONS UNSUITABLE FOR VACCINATION (Persons in whom vaccination is inappropriate) (N/A)	2. PERSONS UNSUITABLE FOR VACCINATION (Persons in whom vaccination is inappropriate) <u>Persons with a history of capillary leak syndrome</u>
8. IMPORTANT PRECAUTIONS Cases of serious thrombosis with thrombocytopenia (sometimes accompanied by bleeding) have been reported following inoculation with this vaccine including very rare forms of venous thrombosis and arterial thrombosis such as cerebral venous sinus thrombosis and splanchnic vein thrombosis. In many of the reported cases, serious thrombosis developed within <u>14</u> days following inoculation with this vaccine, and a fatal outcome resulted in some cases. When vaccinating individuals with risk factors for thromboembolism or thrombocytopenia, benefits and potential risks of immunization should be considered. In addition, from 4th to 28th day post-inoculation with this vaccine particularly, vaccinees should be instructed to be alert for, and seek medical attention immediately if they experience, symptoms such as severe or persistent headache, blurred vision, confusion, seizure, shortness of breath, chest pain, swelling of legs, pain of lower extremities, persistent abdominal pain, as well as non-vaccination site skin haemorrhage or	8. IMPORTANT PRECAUTIONS Cases of serious thrombosis with thrombocytopenia (sometimes accompanied by bleeding) have been reported following inoculation with this vaccine including very rare forms of venous thrombosis and arterial thrombosis such as cerebral venous sinus thrombosis and splanchnic vein thrombosis. In many of the reported cases, serious thrombosis developed within <u>28</u> days following inoculation with this vaccine, and a fatal outcome resulted in some cases. When vaccinating individuals with risk factors for thromboembolism or thrombocytopenia, benefits and potential risks of immunization should be considered. In addition, from 4th to 28th day post-inoculation with this vaccine particularly, vaccinees should be instructed to be alert for, and seek medical attention immediately if they experience, symptoms such as severe or persistent headache, blurred vision, confusion, seizure, shortness of breath, chest pain, swelling of legs, pain of lower extremities, persistent abdominal pain, as well as non-vaccination site skin haemorrhage or

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petechiae. (N/A)	petechiae. Vaccinees in whom thrombocytopenia was observed following inoculation with this vaccine should be thoroughly scrutinized for signs of thrombosis. In addition, platelet counts should be evaluated in vaccinees who developed thrombosis following inoculation with this vaccine. For diagnosis and treatment of thrombosis with thrombocytopenia, appropriate guidelines should be referred to. Although a causal relationship has not been established, very rare cases of capillary leak syndrome have been reported following inoculation with this vaccine. Vaccinees should be instructed in advance to seek medical attention immediately if they experience any symptoms that could suggest capillary leak syndrome (such as oedema extremities, hypotension). Although a causal relationship has not been established, very rare cases of Guillain-Barré syndrome have been reported following inoculation with this vaccine. Vaccinees should be instructed in advance to seek medical attention immediately if they experience any symptoms that could suggest Guillain-Barré syndrome (such as flaccid paralysis starting from distal limb, decreased or absent tendon reflex).
11. ADVERSE REACTIONS	11. ADVERSE REACTIONS

11.1 Other Adverse Reactions Haematologic: Lymphadenopathy 15. OTHER PRECAUTIONS 15.1 Information Based on Clinical Use (N/A)	11.1 Other Adverse Reactions Haematologic: Lymphadenopathy, thrombocytopenia 15. OTHER PRECAUTIONS 15.1 Information Based on Clinical Use Although a causal relationship has not been established, very rare cases of capillary leak syndrome have been reported overseas following inoculation with this vaccine with oedema extremities, hypotension, haemoconcentration, or hypoalbuminaemia as typical symptoms. In addition, these reports included cases of vaccinees with a history of capillary leak syndrome and of fatal outcomes.

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