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*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

## Onasemnogene abeparvovec

March 30, 2021

### **Non-proprietary name**

Onasemnogene abeparvovec

### **Safety measure**

Precautions should be revised in the package insert.

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Revised language is underlined.

Current	Revision
<p>IMPORTANT PRECAUTIONS</p> <p>(N/A)</p> <p>MALFUNCTION/ADVERSE REACTIONS</p> <p>Clinically Significant Adverse Reactions</p> <p>(N/A)</p>	<p>IMPORTANT PRECAUTIONS</p> <p><u>Thrombotic microangiopathy may occur. Patients should be carefully monitored for any signs or symptoms such as purpura, vomiting, or oliguria through methods including periodically performed haematology and renal function tests.</u></p> <p>MALFUNCTION/ADVERSE REACTIONS</p> <p>Clinically Significant Adverse Reactions</p> <p><u>Thrombotic microangiopathy</u></p> <p><u>If anaemia accompanied by schizocytes, thrombocytopenia, renal impairment or any other abnormalities are observed, appropriate measures should be taken.</u></p>

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

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