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Translated by  
Pharmaceuticals and Medical Devices Agency



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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

## Oral live attenuated human rotavirus vaccine

January 17, 2023

### **Therapeutic category**

Vaccines

### **Non-proprietary name**

Oral live attenuated human rotavirus vaccine

### **Safety measure**

Precautions should be revised.

**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
11. ADVERSE REACTIONS (N/A)	11. ADVERSE REACTIONS <u>11.1 Clinically Significant Adverse Reactions</u> <u>Anaphylaxis</u>

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

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