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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

## Frozen-thawed human red blood cells (non-irradiated preparations)

December 17, 2021

### **Therapeutic category**

Human blood preparations

### **Non-proprietary name**

Frozen-thawed human red blood cells

### **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 Biological Products, PMSB/SD Notification No. 004 by the Director of Safety Division, Pharmaceutical and Medical Safety Bureau, MHLW, dated May 20, 2003 (Old instructions): Revised language is underlined.

Current	Revision
<p>Warnings</p> <p>The possibility of developing GVHD (graft versus host disease) due to the use of this drug cannot be ruled out. <u>When blood transfusion is performed in a patient considered to be at a high risk of GVHD,</u> radiation at 15 to 50 Gy should be applied to this drug in advance.</p> <p>Precautions concerning Dosage and Administration</p> <p>(N/A)</p> <p>Adverse Reactions and Infections</p> <p>Clinically Significant Adverse Reactions and Infections</p> <p>GVHD:</p> <p><u>The possibility of developing GVHD due to the use of this drug cannot be ruled out. When blood transfusion is performed in a patient considered to be at a high risk of GVHD, radiation at 15 to 50 Gy should be applied to this drug in advance.</u></p>	<p>Warnings</p> <p>The possibility of developing GVHD (graft versus host disease) due to the use of this drug cannot be ruled out. Radiation at 15 to 50 Gy should be applied to this drug prior to transfusion.</p> <p>Precautions concerning Dosage and Administration</p> <p><u>Irradiation:</u></p> <p><u>Radiation at 15 to 50 Gy should be applied to this drug prior to transfusion.</u></p> <p>Adverse Reactions and Infections</p> <p>Clinically Significant Adverse Reactions and Infections</p> <p>GVHD</p>

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

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