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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Human red blood cells (non-irradiated preparations)

Whole human blood (non-irradiated preparations)

December 17, 2021

Therapeutic category

Human blood preparations

Non-proprietary name

Whole human blood, 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
Warnings Cases of pyrexia and erythema that developed 1 to 2 weeks after transfusion of this drug, followed by death from graft versus host disease (GVHD) accompanied by diarrhoea, hepatic impairment, granulocytopenia, etc. have been rarely reported. 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. (Of note, if radiation is applied to this drug, the level of potassium in the supernatant is increased during storage compared to non-irradiated preparations of this drug. In patients who are likely to experience hyperkalaemia, this drug should be used immediately after irradiation.)	Warnings Cases of pyrexia and erythema that developed 1 to 2 weeks after transfusion of this drug, followed by death from graft versus host disease (GVHD) accompanied by diarrhoea, hepatic impairment, granulocytopenia, etc. have been rarely reported. Radiation at 15 to 50 Gy should be applied to this drug prior to transfusion. (Of note, if radiation is applied to this drug, the level of potassium in the supernatant is increased during storage compared to non-irradiated preparations of this drug. In patients who are likely to experience hyperkalaemia, this drug should be used immediately after irradiation.)
Precautions Concerning Dosage and Administration (N/A)	Precautions Concerning Dosage and Administration Irradiation: Radiation at 15 to 50 Gy should be applied to this drug prior to transfusion.
Adverse Reactions and Infections Clinically Significant Adverse Reactions and Infections GVHD:	Adverse Reactions and Infections Clinically Significant Adverse Reactions and Infections GVHD:

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