This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Non-irradiated blood preparations for transfusion (excluding fresh frozen human plasma)

December 17, 2021

Non-proprietary name

a. Whole human blood
b. Human red blood cells
c. Washed human red blood cells
d. Synthetic blood
e. Concentrated human blood platelet
f. Frozen-thawed human red blood cells

Branded name (Marketing authorization holder)

a. Whole Blood, Leukocytes Reduced, NISSEKI (WB-LR) (Japanese Red Cross Society)
b. Red Blood Cells, Leukocytes Reduced, NISSEKI (RBC-LR) (Japanese Red Cross Society)
c. Washed Red Cells, Leukocytes Reduced, NISSEKI (WRC-LR) (Japanese Red Cross Society)
d. Blood for Exchange Transfusion, Leukocytes Reduced, NISSEKI (BET-LR) (Japanese Red Cross Society)
e. Platelet Concentrate, Leukocytes Reduced, NISSEKI (PC-LR) (Japanese Red Cross Society)
   Platelet Concentrate HLA, Leukocytes Reduced, NISSEKI (PC-HLA-LR) (Japanese Red Cross Society)
f. Frozen Thawed Red Cells, Leukocytes Reduced, NISSEKI (FTRC-LR) (Japanese Red Cross Society)

Pharmaceuticals and Medical Devices Agency
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

Indications

a. Use for indications for general transfusion.

b. Suitable for a red blood cell deficiency or abolition of function.

c. Use for transfusion when anaemia or adverse reactions to plasma components, etc., should be avoided.

d. Use for ABO-blood type incompatibility haemolytic disease of the newborn.

e. Platelet Concentrate, Leukocytes Reduced, NISSEKI (PC-LR): Indicated for diseases accompanied by thrombocytopenia.
Platelet Concentrate HLA, Leukocytes Reduced, NISSEKI: Indicated for diseases with thrombocytopenia in which conventional platelet products are not effective because of the presence of anti-HLA antibodies.

f. Use for anaemia or defective function of red blood cell.

Summary of revisions

1. The language concerning the scope of precaution associated with irradiation of this drug prior to transfusion should be deleted from the statement regarding graft versus host disease (GVHD) in the WARNINGS section.
2. "Irradiation" should be newly added to the PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION section and the language "radiation at 15 to 50 Gy should be applied to this drug prior to transfusion" should be added.
3. The statement that radiation at 15 to 50 Gy should be applied to this drug in advance when blood transfusion is performed in a patient considered to be at a high risk of GVHD should be deleted from "GVHD" in the Clinically Significant Adverse Reactions and Infections section.

Investigation results and background of the revision

The WARNINGS section and Clinically Significant Adverse Reactions and Infection section of the package insert include precautionary statements regarding prevention of GVHD. In the precautionary statements, those considered to be at a high risk of GVHD are specified as patients requiring irradiation in advance; however, in Guidelines for Blood Transfusion Therapy, Guidelines for Blood Product Use, and Guidelines V on Irradiation of Blood to Prevent GVHD Due to Transfusion, all transfusion patients are included, thus the presence

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

of discrepancies between the current package inserts and guidelines has been confirmed. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

No cases have been reported to date.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the "Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency" (PMDA Administrative Rule No. 20-8, dated December 25, 2008).