Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Review

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Change Orders

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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: RED CELLS, RESUSPENDED

Change Description:
Revise the Labelling and Barcode Illustrations.

Reason for Change:
To update the PMFs with new Label Versions (Ref CC 208/23 & 002/24)

Change order No.:
IBTS/CO/0219/25

Referenced Documents
N/A

SmartSolve Roles
N/A

Training Type
N/A

SmartSolve Document Category

Category	Mobile	Cryobiology	Website	GDP
Yes / No	No	No	Yes	No

IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

Title: **Red Cells, Resuspended**

Name of Product: **RED CELLS, Resuspended**

E Progesa Codabar Component Code: **04454**

E Progesa ISBT-128 Component Code: **E8214V00**

General Description: A red cell suspension obtained from leucodepleted whole blood collected into CPD which is reprocessed during its shelf life (up to Day 10 post donation) by centrifugation and removal of plasma with subsequent addition of an additive solution SAG-M.

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	255 - 365 ml	100%
Haematocrit	0.50 - 0.70 L/L	1%
Haemoglobin	$\geq$ 40 g/unit	1%
Leucocyte Content	< 1 x 10^6/unit	Counted in parent units (03151/C6468V00) 1 per week
Haemolysis at end of shelf life	< 0.8% of red cell mass	2 per month

Labelling: See Appendix 1

Storage: Red Cells, Resuspended should be stored at 4°C $\pm$ 2°C. The storage time is 28 days.

Irradiation: Red Cells, Resuspended are **never irradiated**.

Transportation: The air temperature of transport containers for units of Red Cells Resuspended should be maintained between 2°C and 10°C during transport from The Irish Blood Transfusion Service to the place that they are intended for use. Transport time under these conditions normally should not exceed 8 hours.

Indications for Use: Red Cells, Resuspended are used to augment the oxygen delivery capacity of the blood where this is critically impaired.

Precautions in Use:

- Compatibility of this component with the intended recipient must be verified by suitable pre transfusion testing.
- Red Cells, Resuspended should be infused intravenously through a set containing an inline 170-200 µm filter.
- No solution should be added to the bag or to the giving set.
- Components should be inspected visually for defects, leakage, abnormal colour or visible clots.
- Red Cells, Resuspended are **not** recommended in:
  - various types of plasma intolerance (may not apply to units with a low plasma content);

Adverse Effects Include:

- Circulatory Overload.
- Haemolytic transfusion reaction;
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria). The risk is reduced by leucodepletion
- Anaphylaxis
- Pathogen transmission
  - Despite careful donor selection and laboratory screening procedures, infections including Syphilis, Viral Hepatitis, HIV, HTLV 1 & 11 and other viruses and protozoa (e.g. malaria) may, in rare instances, occur.
  - vCJD transmission
  - Transmission of other pathogens that are not tested for or recognised.
  - The risk of CMV transmission is minimal as the components are leucodepleted
  - Sepsis due to bacterial contamination (reduced but not eliminated by bacterial screening)
- Metabolic upset
  - Possible elevated potassium level in massive transfusions, especially where patient is hypothermic or acidotic or has impaired renal function.
  - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.
  - Hypocalcaemia.
  - Hypoglycaemia.
  - Hypokalaemia.

- Immunological effects
  - Alloimunisation to HLA and red cell antigens.
  - Graft vs Host Disease (GvHD) in immuno compromised recipients . The risk of GvHD is eliminated by irradiation
  - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies.
  - Post transfusion purpura (PTP).

- Iron overload
  - In patients on chronic red cell transfusion support programmes.

Serious Adverse Reaction
Please inform the IBTS immediately about any event relating to suspected bacterial sepsis/ transfusion associated bacterial sepsis

Serious adverse reactions should be reported to:

National Haemovigilance Office
Irish Blood Transfusion Service
National Blood Centre
James's Street
Dublin 8

AND

Quality Assurance Manager
Irish Blood Transfusion Service

AT EITHER
National Blood Centre
James's Street
Dublin 8

OR
Munster Regional Transfusion Centre
St Finbarr's Hospital
Douglas Road, Cork

APPENDIX 1

E Progesa Codabar Component Code : 04454

E Progesa ISBT -128 Component Code: E8214V00

Product Name
RED CELLS, Resuspended

Shelf Life
28 days

Labelling and Barcodes:
(for illustration purposes only – barcodes not suitable for scanning – label not to scale)