Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Title: **WHOLE BLOOD, RECONSTITUTED, SUITABLE FOR NEONATAL USE**
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Review

Review: IBTS PMF REVIEW

Level	Owner Role	Actor	Sign-off By
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Change Orders

Changes as described on Change Order:	Change Order No.

Change Orders - Incorporated

Changes as described on Change Order:	Change Order No.
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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: **WHOLE BLOOD, RECONSTITUTED, SUITABLE FOR NEONATAL USE**

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: **Whole Blood, Reconstituted, Suitable for Neonatal Use**

Name of Products: **WHOLE BLOOD, Reconstituted, Suitable for Neonatal Use. HCT:….**

WHOLE BLOOD, Reconstituted, Suitable for Neonatal Use, Irradiated. HCT:….

E Progesa Codabar Component Codes : **54270 / 54271**

E Progesa ISBT – 128 Component Codes : **E8211V00 / E8213V00**

General Description: This component is prepared by combining a unit of red cells (following removal of additive solution) with a unit of thawed fresh frozen plasma (group AB). The donors of the selected components meet the additional criteria as being suitable for neonatal use..

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	>340 mL	100%
Haematocrit	≥0.35 L/L	100%
Haemoglobin	≥ 40 g/unit	100%
Leucocyte Content	< 1 x 10^6 / unit	Counted in units of red cells (04333/E7429V00)
Haemolysis at end of shelf life	< 0.8% of red cell mass	100%
ABO Agglutinins	No High Titre Anti-A or Anti-B	100%
CMV	CMV ab negative	100%

Labelling: See Appendix I

Storage: Whole Blood, Reconstituted, Suitable for Neonatal Use. HCT:… / Whole Blood, Reconstituted, Suitable for Neonatal Use, Irradiated, HCT:…should be stored at $4^oC \pm 2^{oC.}$

Irradiation: Whole Blood, Reconstituted, Suitable for Neonatal Use HCT:…should be irradiated before transfusion provided this does not unduly delay the transfusion. Post irradiation the component code changes to 54271/E8213V00 and the product should be used within 6 hours. It **must** be irradiated prior to transfusion where the neonate has had a previous intrauterine transfusion.

Transportation: The air temperature of transport containers for units of Whole Blood, Reconstituted, Suitable for Neonatal Use HCT:… / Whole Blood, Reconstituted, Suitable for Neonatal Use, Irradiated, HCT:… should be maintained between 2°C and 10°C during transport from the Irish Blood Transfusion Service to the place where they are intended for use. Transport time under these conditions normally should not exceed 8 hours.

Indications for Use: Whole Blood, Reconstituted, Suitable for Neonatal Use HCT:… / Whole Blood, Reconstituted, Suitable for Neonatal Use, HCT:… Irradiated, is suitable for exchange transfusion and is used to augment the oxygen delivery capacity of the blood where this is critically impaired.

Precautions in Use:

- Compatibility of red cells with the intended recipient must be verified by suitable pretransfusion testing.
- Red Cells, Washed / Red Cells, Washed, Irradiated should be infused intravenously through a set containing an inline 170-200 µm filter.
- No other solutions should be added to the bag or giving set.
- Components should be inspected visually for defects, leakage, abnormal colour or visible clots.

Adverse Effects Include:

- Circulatory Overload.
- Haemolytic transfusion reaction;
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria).

The risk is reduced by leucodepletion and washing

- <u>Pathogen transmission</u>
  - 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 I

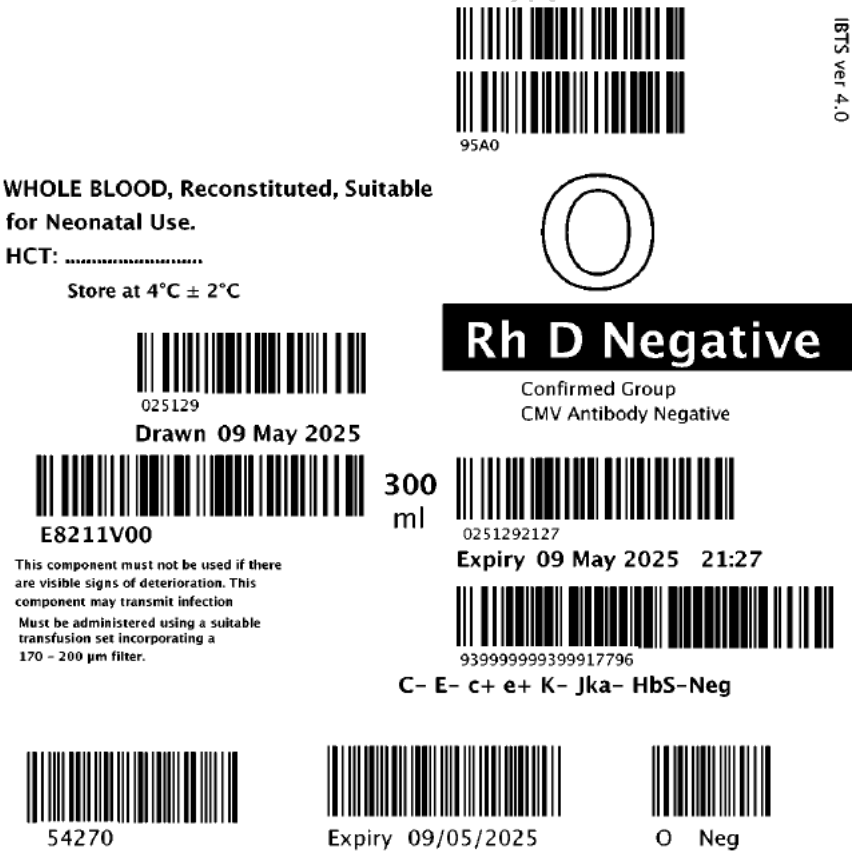
E Progesa Codabar Component Code: 54270

E Progesa ISBT – 128 Component Code : E8211V00

Product Name
WHOLE BLOOD, Reconstituted, Suitable for Neonatal Use
HCT:…..

Shelf life
6 hours

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



APPENDIX I

E Progesa Codabar Component Code: 54271

E Progesa ISBT – 128 Component Code: E8213V00

Product Name
WHOLE BLOOD, Reconstituted, Suitable for Neonatal Use, Irradiated
HCT:…..

Shelf life
6 hours

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