



Irish Blood Transfusion Service

Seirbhís Fuilaidriúcháin na hÉireann

Document Detail

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

Review: IBTS PMF REVIEW

| <u>Level</u> | <u>Owner Role</u> | <u>Actor</u> | <u>Sign-off By</u> |
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Review: IBTS DOC PERIODIC REVIEW

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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.**
IBTS/CO/0229/21

**IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE**

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

Change Description:

Revise IBTS/PMF/SPEC/0203 to IBTS/PMF/SPEC/0212 and IBTS/PMF/SPEC/0232 to amend the product labels.

Reason for Change:

Fix to the labels with reference to IR 361/21/IBTS, IBTS/QA/PQ/0600 Deviation 012 and CC 134/21/IBTS

Change order No.:

IBTS/CO/0229/21

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 | $< 1 \times 10^6$ / 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 $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

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

- 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
 - Alloimmunisation 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)

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

Store at 4°C ± 2°C

O

Rh D Positive
CMV Antibody Negative

200 ml

Expiry 05 May 2021 19:09

C+ c- E- e+ K- HbS-Neg

54270

Expiry 05/05/2021

O Pos

This component must not be used if there are visible signs of deterioration. This component may transmit infection. Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter.

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)



IBTS ver 3.0

WHOLE BLOOD, Reconstituted, Suitable for Neonatal Use, Irradiated.



HCT:

Store at 4°C ± 2°C



Drawn 05 May 2021

Rh D Positive

IRRADIATED (24 H)
CMV Antibody Negative



200 ml



Expiry 05 May 2021 19:10

This component must not be used if there are visible signs of deterioration. This component may transmit infection. Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter.



C- c+ E+ e- K- HbS-Neg

